Improving Contraceptive Method Choice and Use with a Computer-Based Contraceptive Assessment Module

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ABSTRACT

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Unintended pregnancy [1] is prevalent and persistent in the United States [2-4], with significant public health costs [5-20]. Paralleling disparities in other reproductive health outcomes, some population subgroups are more likely to have an unintended pregnancy than others. Use of highly effective contraceptive methods can reduce unintended pregnancy rates [21-23]. Interventions to help those at highest risk of unintended pregnancy are of critical public health importance, yet few interventions have been found to significantly impact contraceptive method choice and use, and even fewer have been designed for populations with low educational attainment. The current dissertation research was designed to meet the need for interventions appropriate for women with low educational attainment, addressing a significant gap in the literature on interventions to improve contraceptive choice and use.

A three-arm randomized controlled trial of a bilingual (Spanish/English) contraceptive assessment module using audio-computer-assisted self-interviewing technology and touchscreen computers was conducted from March 2008 – January 2011 among family planning patients seeking care at two federally-funded family planning clinics in New York City. The three-arm design was used to test separately the effect of the assessment module and the effect of tailored health materials: participants were randomized to complete the module and received health information materials tailored to their responses to the module questions (Intervention + Tailored); to complete the module and receive generic material (Intervention + Generic); or to a control condition (Control). Contraceptive method choice on the day of the family planning visit was the primary outcome. Follow-up analyses among a randomly-selected subset of patients examined secondary outcomes, including continuation and adherence to the chosen contraceptive method 4 months after the family planning visit.

In intent-to-treat analyses adjusted for clinical recruitment site (n=2,231), family planning patients who used the module were significantly more likely to choose an effective contraceptive method (a method with fewer than 10 pregnancies among 100 women in one year typical use): 75% among those who received tailored materials [Intervention + Tailored OR=1.56 (95% CI: 1.23-1.98)] and 78% among those who received generic materials [Intervention + Generic OR=1.74 (95% CI: 1.35-2.25)], compared to 65% among control arm participants. Tailored health information materials, compared to generic materials, did not have significant impact on contraceptive method choice. These findings were consistent in as-treated analyses among participants who completed the module and data collection procedures on the day of their family planning visit, in analyses comparing different sources of outcome data, and in sensitivity analyses accounting for missing outcome data.

In a subset of participants randomly selected for participation in a follow-up survey 4 months after their family planning visit (n=224), those in the Intervention + Tailored arm were significantly more likely to continue use of the contraceptive method chosen on the day of their family planning visit, with 95% continuing use, compared to 77% in the Control arm (OR adjusted for clinical site of recruitment = 5.48 [95%CI: 1.72-17.42]). No significant difference in continuation was found between the Intervention + Generic and Control arms.

The dissertation research has numerous strengths. The easily replicable, single-session intervention was designed for use by populations with low educational attainment or low literacy skills. The randomized controlled trial included more than 2,000 family planning patients, half of whom were Spanish-speaking. Effectiveness research evaluating the impact of the intervention under “real-world” conditions of implementation, in a broadly defined population, is merited. Such evaluation should include measures not fully explored in this phase, including the impact of the module on provider visit time, and analyses of continuation and adherence outcomes over a longer period of time.

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ACKNOWLEDGMENTS

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This dissertation is dedicated to my mentors, professional and personal, without whom this work would not have been possible:

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1 CHAPTER 1: RATIONALE & BACKGROUND

1.A RATIONALE

1.A.1 Unintended Pregnancy

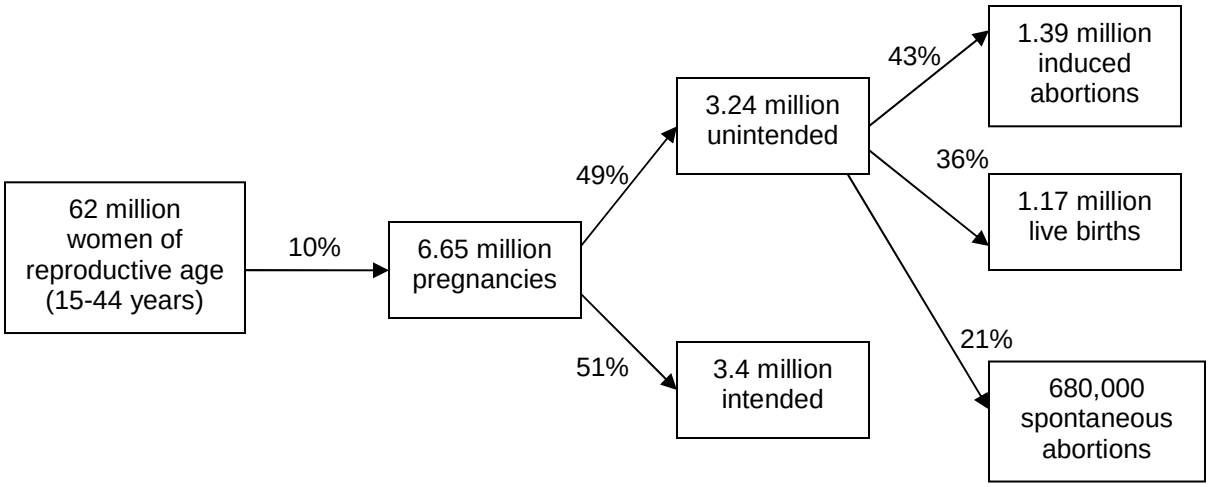
The National Survey of Family Growth (NSFG) – a periodic national survey by the CDC's National Center for Health Statistics (NCHS) conducted first in 1973 and most recently in 2006-2008 – asks a series of retrospective questions to categorize pregnancies as intended, mistimed (occurring earlier than desired), or unwanted (occurring to women who did not want to become pregnant at the time of conception or in the future) [24]. Pregnancies that are mistimed or unwanted are conventionally classified as unintended [1, 19, 25-30]. The conventional classification of unintended pregnancy, while widely used, does not adequately capture the complexity of pregnancy intention status, as it overlooks key factors such as the timing of the measurement (prospective or retrospective), the extent of the mistiming of the pregnancy, family-level characteristics, contextual factors such as poverty or gender inequality, or the pregnancy intention of the male partner [1, 27, 31].

1.A.2 Unintended Pregnancy: Prevalence and Trends

Unintended pregnancy is widespread in the United States. A full 10 percent of the 62 million women of reproductive age (15-44 years) in the US get pregnant each year [32], and half of pregnancies are estimated to be unintended [33]. The proportion of pregnancies that are unintended has not declined in the last decade [2-4]. As shown in Figure 1-1, unintended

pregnancies that occurred in 2006 – 49% of all pregnancies – resulted in almost 1.2 million live births and 1.4 million induced abortions [3].

Figure 1-1. Pregnancies in the United States in 2006, by intention status and outcome



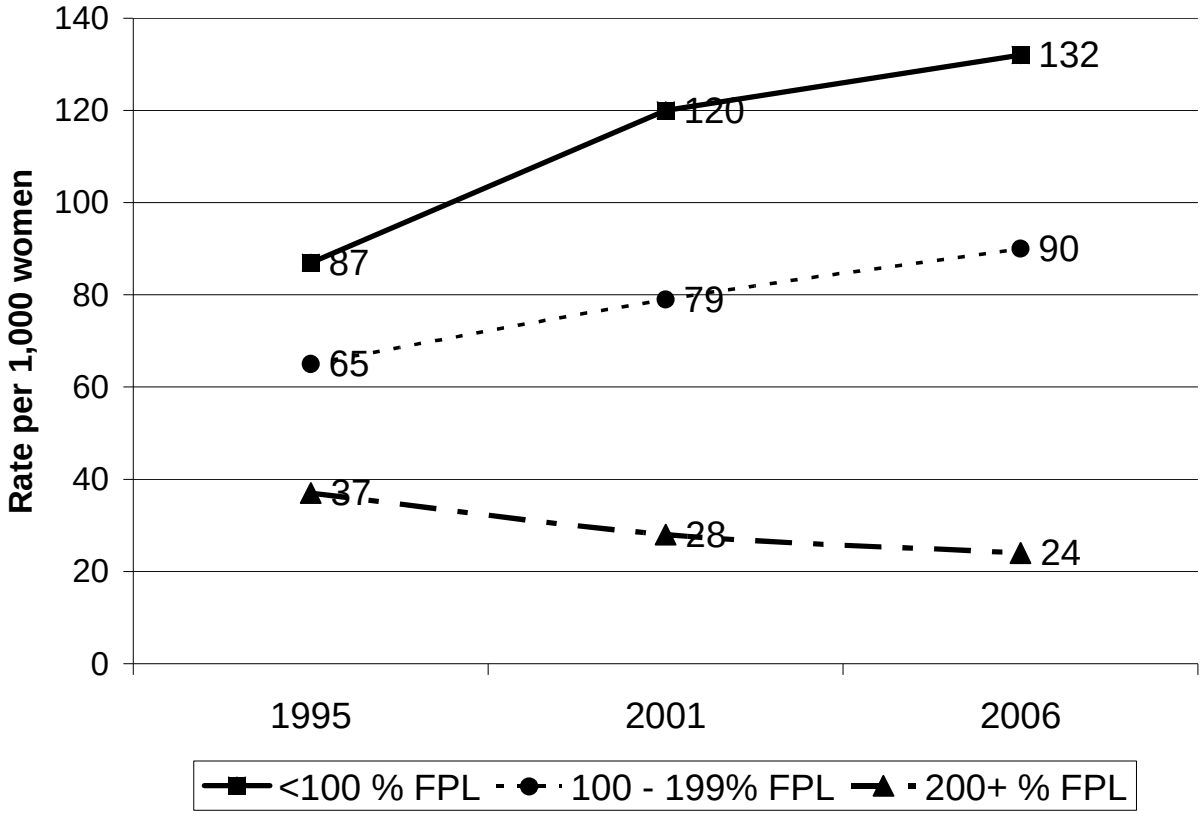
Note: *Figure compiled from data in published reports [3, 32]*

Nationally, millions of women are at risk of unintended pregnancy. Of the 62 million women of reproductive age in the United States [Figure 1-1], the most recent (2006-08) NSFG findings estimated that 43 million are sexually active but do not wish to become pregnant [32].

1.A.3 Disparities in Unintended Pregnancy

Paralleling disparities in other reproductive health outcomes, some population subgroups are more likely to have an unintended pregnancy than others. Young women, low-income women, Latinas, non-Latina black women, unmarried women, and women with lower educational attainment have higher rates of unintended pregnancy; in turn, they also have higher rates of induced abortion [2, 23, 34]. Socioeconomic differences in unintended pregnancy are stark, and have widened since the mid-1990s, as shown in Figure 1-2 [2, 35]. In 2006, women with incomes below the federal poverty level had a rate of unintended pregnancy that was more than 5 times higher than that among women with incomes 200% or more of the poverty level.

Figure 1-2. Rates of unintended pregnancy 1995 - 2006, by federal poverty level (FPL)



Notes: *Figure compiled from data in published reports [2, 3]. Unadjusted rates are specific to the population of women of reproductive age in the year indicated.*

Racial and ethnic disparities persist after taking into account these socioeconomic differences [34]. Analogous to disparities in birth rates [36, 37], non-Latina black women and Latina women (of any race), compared to non-Latina white women, are significantly more likely to report having had an unintended pregnancy, even after controlling for socioeconomic factors [38].

Finally, young women – teenagers (age 15-19) and women age 20-24 – are significantly more likely than women in older age groups to have a mistimed or unwanted pregnancy [39-42], both in terms of rates and proportions. The rate of unintended pregnancy among teenagers in 2006 was 60 per 100,000 women (with 82% of 769,000 pregnancies unintended) and for

women age 20-24, it was 107 per 100,000 women (with 64% of 1.7 million pregnancies unintended), compared to a rate of 46 per 100,000 women age 30-34 (with 33% of 1.33 million pregnancies unintended) [3].

1.A.4 Public Health and Social Costs of Unintended Pregnancy

Unintended pregnancy represents a significant public health concern, not only because of its prevalence but because of the costs – financial, medical, and social – associated with it. Several systematic reviews have examined the relationship between pregnancy intention status and behavioral health during pregnancy, birth outcomes, and maternal behaviors and child health after birth, with substantial differences found among those whose pregnancies were intended, mistimed and unwanted [14, 41, 43]. Pregnancy intention is associated with maternal behaviors during pregnancy that, in turn, influence birth outcomes. Analyses taking into account sociodemographic and other confounders have found that during pregnancy, women with an unintended pregnancy were more likely than women whose pregnancies were intended to smoke cigarettes, more likely to binge drink, less likely to consume daily prenatal vitamins including folic acid (to prevent neural tube defects), and less likely to gain the recommended amount of weight, with some differences explained by differences in the timing of initiation of prenatal care [10, 16, 17, 44, 45].

Unintended pregnancies have also been found to be more likely to result in adverse birth outcomes. A systematic review of 15 published studies found significantly increased odds of both low birthweight (<2500 grams) and preterm birth (<37 weeks gestation) among births to women with unintended pregnancies compared to births to women with intended pregnancies, and results persisted after adjustment for clinical predictors of low birthweight [20].

Research has also found that the adverse effects of unintended pregnancy persist after delivery: compared to women whose pregnancies were intended, mothers who carry unintended pregnancies to term were less likely to breastfeed their infants [10, 12, 13, 41] and more likely to suffer from postpartum depression [10]. Pregnancy intention affects children through young adulthood, with longitudinal studies finding that children and young adults whose births were the result of unintended pregnancies, compared to those whose births resulted from intended pregnancies, were more likely to have low self-esteem [8], to have siblings with behavioral problems in school [9], to have poorer health status [46], to have psychiatric problems [5, 47, 48], and to have lower scores on cognitive functioning scales [49], although not all evidence suggests that these effects persist into later childhood and young adulthood [50].

Unintended pregnancy has economic costs, as well. Unintended births contribute to a cycle of socioeconomic disadvantage for both mothers and children, as a result of deferred educational and employment opportunities [34, 51-53]. Two separate analyses published in 2011, taking into account the fact that 64% of births resulting from unintended pregnancies occur among women receiving publicly funded health insurance (compared to 35% of births resulting from intended pregnancies covered by publicly funded health insurance), estimated that the annual cost to US taxpayers of births resulting from unintended pregnancies was $11 billion [6, 15].

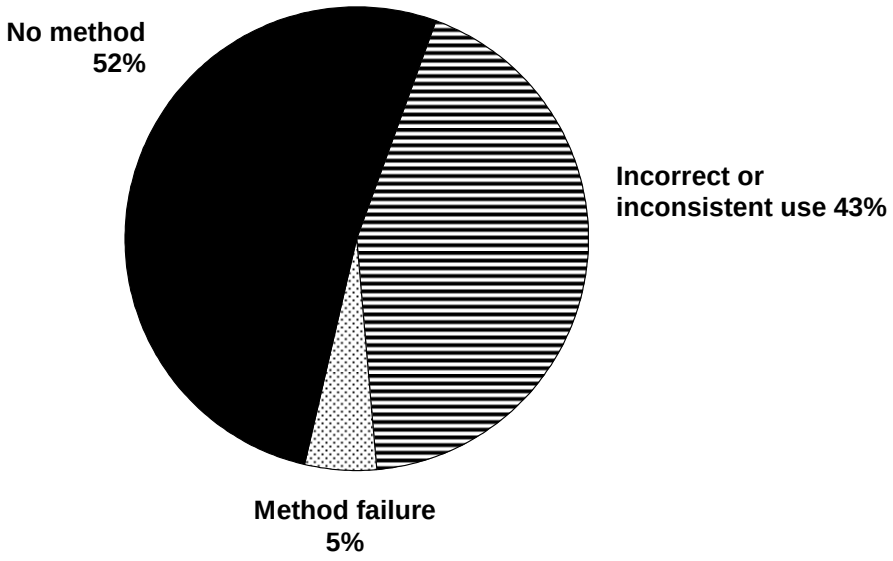
1.A.5 Contraceptive Use and Unintended Pregnancy

Contraceptive choice and use are essential intermediate behavioral outcomes in reducing unintended pregnancy. The Centers for Disease Control and Prevention identified family planning as one of the greatest public health achievements of the twentieth century, allowing women and men to achieve their desired family size and spacing of children [54-56]. An estimated 1.5 million unintended pregnancies are averted each year in the US through the

availability of contraception in federally-funded family planning clinics [57]. The decline in teen pregnancy rates from the 1990s to the mid-2000s has been attributed primarily to improved contraceptive use among adolescents [58, 59].

Yet reducing the incidence of unintended pregnancy remains a challenge: Healthy People 2020 includes a goal of increasing the proportion of pregnancies that are intended through the use of contraception, but to date no state has achieved the goal [60]. As shown in Figure 1-3, slightly more than half (52%) of all unintended pregnancies in 2001 occurred among women not using any method of contraception, while only 5% occurred among women using contraception correctly and consistently [2, 33].[a]

Figure 1-3. Contraceptive use status of women with unintended pregnancies in 2001



Note: *Figure compiled from data in published reports [2, 33]*

[a] Published analyses to date from the most recent cycle (2006-08) of the NSFG have not yet assessed data on contraceptive use status by pregnancy intention.

1.A.6 Disparities in contraceptive use

Socioeconomic and sociodemographic differences in contraceptive use parallel those of unintended pregnancy, with low-income women, Latinas, non-Latina blacks, young women, and those with lower educational attainment less likely to use contraception, and less likely to rely on effective contraceptive methods [32, 61, 62]. Among women currently using contraception, those of low socioeconomic status have been found to be more likely to experience contraceptive failure or inconsistent use due to financial or health care barriers, compounding disparities in unintended pregnancies [23, 25, 33, 63, 64]. Contraceptive use among teenagers, consistently lower than among older age groups, has changed little between the two most recent cycles of the NSFG [39, 65].

1.B BACKGROUND

1.B.1 Need for Contraceptive Counseling Interventions

Given the prevalence of unintended pregnancy, the persistent social, health and economic costs, and the strong link between contraceptive non-use and unintended pregnancy, developing interventions to improve contraceptive method choice and use is of critical public health importance.

Contraceptive decisionmaking is a complex process for both the patient and the provider [66]. Contraceptive counseling interventions need to communicate key information about method effectiveness [67-69], but effectiveness is not the sole consideration in the method counseling process. Medical risks – for example, a history of deep vein thrombosis as a contraindication for oral contraceptives [70-73] – must also be taken into consideration. The CDC recently adapted the World Health Organization (WHO)'s Medical Eligibility Criteria, which provide clinical guidance regarding safe use of contraceptive methods given medical conditions, for use in the United States [70, 71]. In addition to medical conditions and contraindications,

personal preferences – such as relationship status, childbearing expectations, or how frequently a woman wishes to take action for contraception – also influence contraceptive method choice, and, in turn, use [33, 74-78].

1.B.2 Contribution of Dissertation Research to Evidence Base on Interventions to Improve Contraceptive Choice and Use

As summarized below, the current dissertation research was designed to meet the need for interventions appropriate for women with low educational attainment and/or low literacy skills, addressing a significant gap in the literature on interventions to improve contraceptive choice and use. Of the 72 interventions examined in the systematic reviews summarized in Table 1-1, less than one-fourth found a positive impact on contraceptive outcomes of any kind, and only one of these interventions was specifically designed for use with low literacy populations.

1.B.3 Literature Search of Interventions to Improve Contraceptive Choice

To address the complexity of incorporating these considerations into method counseling, interventions and decisionmaking tools have been developed, and tested in various settings. A literature review of interventions to improve contraceptive choice or use was conducted as an initial step of the dissertation. In the 11 years since 2000, five widely-cited systematic reviews have been published: a systematic review of more than 350 articles on counseling to reduce unintended pregnancy published between 1985 and 2000 [79]; a review by the United States Preventive Task Force on counseling interventions to reduce transmission of sexually transmitted infections [80]; a Cochrane database review on strategies to improve use and adherence of hormonal contraceptive methods [81]; another Cochrane database review on communicating contraceptive effectiveness information [68]; and a review of theory-based interventions, conducted by the lead author of the 2008 Cochrane database review [82].

In order to identify interventions that may not have been included in these published reviews, a Medline search using the terms [“contraceptive choice” and “intervention”] or [“contraceptive use” and “intervention”] or [“contraceptive decision-making” and “intervention”] or [“contraceptive counseling” and “intervention”] published in English-language Medline-indexed publications from 2000 through April 2011 produced 29 additional references. To supplement the database search process, the references of these 29 articles were reviewed and 2 more review articles and 5 additional publications of interventions published since 2000 (for a total of 34) were identified and reviewed. After excluding papers describing interventions not relating to contraceptive counseling or not including contraceptive behavior, contraceptive knowledge, or pregnancy outcomes (n=9); duplicate publications from the same study (n=2); interventions not tested in the United States (while the Cochrane reviews included non-US studies [68, 81, 83], the decision to exclude non-US studies was consistent with guidelines of the Moos review [79], n=12); and descriptive studies that did not compare the intervention to a control condition (n=1), 10 publications of intervention studies were identified, of which only 3 had not been included in the published systematic reviews. There is a substantial body of literature on interventions to reduce transmissions of sexually transmitted infections such as HIV through the use of condoms, abstinence, or changes in sexual behavior [84-91]; only articles identified through the process described above were included in the literature review summary in this Chapter. The scope and findings of the 7 published systematic reviews are summarized in Table 1-1.

Table 1-1. Summary of scopes and findings of published systematic reviews of contraceptive counseling interventions

Systematic Review Title (Author, Year)	Scope of review (Years)	Outcomes studied	Number of interven-tions with significant difference	Summary of findings
Interventions to reduce unintended pregnancies among adolescents: systematic review of randomized controlled trials (DiCenso, 2002 [92])	Full articles: 26 Meta-analyses: 22 RCTs (1970-2000)	Behavior: initiation of sex	0 of 14	Among 14 interventions with 9,642 participants, no significant effect in individual studies or pooled analyses.
		Behavior: always use of birth control	0 of 8	Among 8 interventions with 1,967 females and 1505 males, no significant effect in individual studies or pooled analyses.
		Behavior: birth control at last sex	1 of 6	The school-based intervention included 8 sessions among junior high school students [93]. No significant findings in pooled analyses.
	Full articles: 26 Meta-analyses: 22 RCTs (1970-2000)	Outcome: pregnancy rates (participants)	1 of 12	Among 12 interventions with than 8,000 young women, only 1 high-intensity, multifaceted intervention had significant reduction in pregnancy rates [94]. No significant findings in pooled analyses.
		Outcome: pregnancy rates (partners)	1 of 5	The theory-driven, school-based abstinence intervention, conducted in 8 sessions over 2 weeks, resulted in a reduction in pregnancies among the partners of male participants [95]. Pooled analyses (3,759 males participants) also found positive effect (pooled OR: 1.54, 95%CI: 1.03-2.29).

Table 1-1, Continued

Systematic Review Title (Author, Year)	Scope of review (Years)	Outcomes studied	Number of interven-tions with significant difference	Summary of findings
Counseling in the clinical setting to prevent unintended pregnancy: an evidence-based research agenda (Moos, 2003 [79])	Abstracts: 673 Full articles: 354 Evidence review: 74 Evidence tables: 13 interventions (1 RCT) (1985-2000)	Knowledge: contraceptive knowledge	2 of 3	In the only RCT studied [96], male adolescent participants who viewed a slide presentation had better knowledge, but did not translate into changes in behavior. A one-on-one educational intervention over 2 sessions among 1,256 teens [97] found increased knowledge after 6 months.
		Attitude: locus of control	0 of 1	A small study of 79 pregnant teens did not find an effect from individual and group counseling [98].
	Abstracts: 673 Full articles: 354 Evidence review: 74 Evidence tables: 13 interventions (1 RCT) (1985-2000)	Behavior: contraceptive compliance and continuation	3 of 9	Heterogeneous behavior outcomes were studied: Among 1819 women, face-to-face education with expanded nursing care resulted in improved condom use [99]. A study of contingency counseling found an increase in effective pill use 6 months after the intervention, but not after 12 months [100]. A two-session counseling intervention among teens found higher rates of continuation of the chosen method at both 6 and 12 months [97].
		Outcome: unintended pregnancy	1 of 1	Among 914 family planning patients, those who received contingency counseling had a significant reduction in unintended pregnancy at 6 months, but no effect was seen after 12 months [100].

Table 1-1, Continued

Systematic Review Title (Author, Year)	Scope of review (Years)	Outcomes studied	Number of interven-tions with significant difference	Summary of findings
Behavioral counseling to prevent sexually transmitted infections (Lin, 2008 [80])	Abstracts: 3,197 Full articles: 287 Evidence tables: 3 RCTs with sex behavior outcomes (1988 - 2008)	Behavior: condom use	1 of 3	Only 1 of the 3 studies found an effect of structured counseling on sex behavior: those receiving "extremely intensive (p. 4)" counseling were less likely to engage in unprotected sexual intercourse [101].
Strategies for communicating contraceptive effectiveness (Lopez, 2008 [68])	Full articles: 27 Evidence tables: 5 RCTs (1984-2007)	Knowledge: knowledge of effectiveness of methods	4 of 5	In the 4 studies, counseling with audiovisual aids was more effective than oral information [69, 102, 103].
		Behavior: contraceptive method choice	1 of 5	Only 1 study [104] found effect on choice: those who received expanded counseling were more likely to choose a method of contraception, compared to standard counseling (OR 2.35, 95%CI: 1.82-3.03).
The impact of programs to increase contraceptive use among adult women: a review of experimental and quasi-experimental studies (Kirby, 2008 [105])	Evidence tables: 3 counseling or reminder studies (1 RCT) (1990-2005)	Behavior: contraceptive adherence	1 of 3	A quasi-experimental study found that participants who received a reminder postcard were more likely to get Depo-Provera injections on time [106].
		Outcome: pregnancy rate	0 of 1	In an RCT, no impact of theory-based structured counseling on pregnancy rates [107].

Table 1-1, Continued

Systematic Review Title (Author, Year)	Scope of review (Years)	Outcomes studied	Number of interven-tions with significant difference	Summary of findings
Theory-based strategies for improving contraceptive use: a systematic review (Lopez, 2011 [82, 83])	Evidence tables: 14 RCTs (1981-2010)	Behavior: contraceptive adherence	2 of 4	The effective interventions using motivational interviewing – one single-session [108] and one with 4 sessions [109] – by the same team of researchers focused on college aged students at risk of an alcohol-exposed pregnancy; the counseling interventions resulted in more effective use of contraception compared to receiving a brochure.
		Behavior: contraception used at last sex	2 of 7	A school-based intervention among 3,689 students using Social Cognitive Theory found a higher proportion used any method contraception at last sex [110]. A cognitive-behavioral intervention conducted among teens in the late 1970s – which entailed 14 50-minute sessions – found more frequent use of more effective methods at last sex [111].
		Behavior: condom use at last sex	3 of 8	The same Social Cognitive Theory intervention also found higher rates of condom use at last sex [110]. A second intervention by the same researchers, incorporating other theories, also found higher rates of condom use.

Table 1-1, Continued

Systematic Review Title (Author, Year)	Scope of review (Years)	Outcomes studied	Number of interven-tions with significant difference	Summary of findings
Theory-based strategies for improving contraceptive use: a systematic review (Lopez, 2011 [82, 83]) *Continued*	Evidence tables: 14 RCTs (1981-2010)	Outcome: pregnancy rate	2 of 10	One intervention, consisting of biweekly sessions conducted over one year among African American adolescent mothers, found lower rates of second births 24 months after baseline compared to the control group [112]. Another intervention among African American adolescents found lower rates of pregnancy (or "getting someone pregnant") over 24 months among those who participated in group meetings with sessions for parents compared to just group sessions [113].
Strategies to improve adherence and acceptability of hormonal methods of contraception (Halpern, 2011 [81, 114])	Full articles: 19 Evidence tables: 8 RCTs (1982 – 2010)	Behavior: contraceptive method continuation	1 of 8	Half of the studies reviewed had high loss to follow-up, and 3 had small sample sizes. One study found higher rates of continuation of Depo-Provera among those who received structured counseling regarding the method, compared to routine counseling [115].

Note: *RCT = randomized controlled trial*

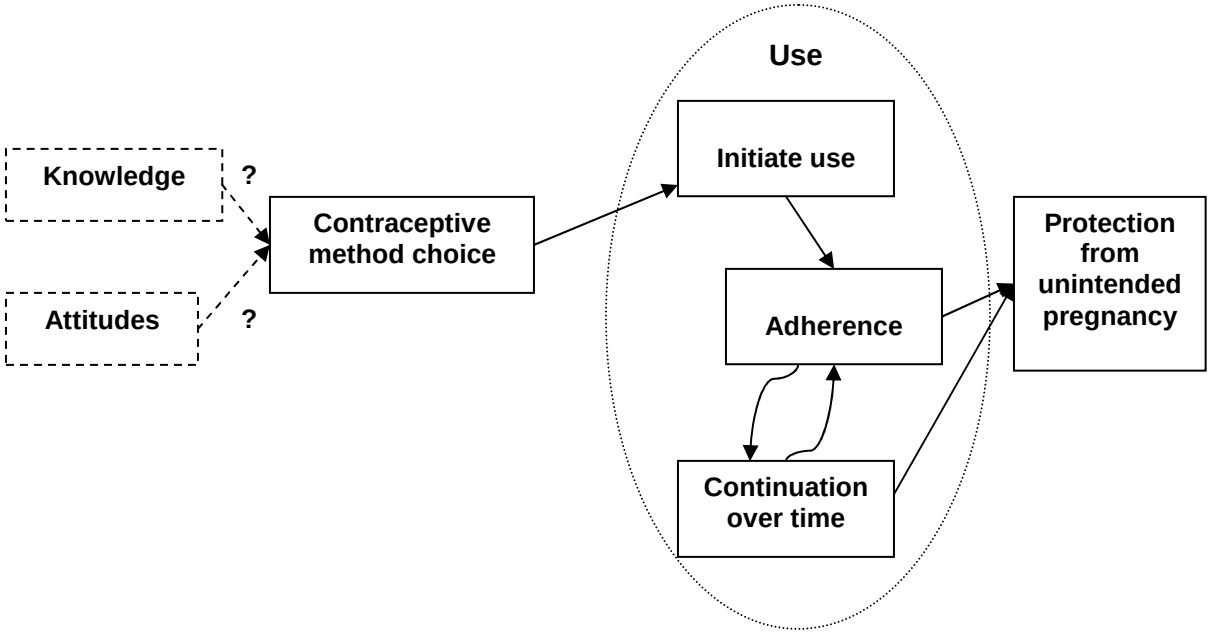
1.B.4 Impact of Interventions on Contraceptive Outcomes

1.B.4.a Understanding contraceptive outcomes

The heterogeneity of outcomes included in the systematic reviews outlined in Table 1-1 presented a challenge to drawing conclusions about the effectiveness of interventions in reducing unintended pregnancy [79, 81]. Figure 1-4 conceptually outlines how the various

contraceptive outcomes examined in the studies summarized in Table 1-1 relate to the long-term goal of reducing unintended pregnancy. Interventions that have the long-term goal of reducing unintended pregnancy – an outcome that is not only complex to measure [1, 19, 25-30] but also one that requires sufficient statistical power to detect – may use intermediate outcomes such as contraceptive choice, adherence (the correct, consistent use of the contraceptive method as prescribed or instructed, also referred to as compliance [116-118]), or continued use over time, all factors that determine protection from unintended pregnancy [117, 119].

Figure 1-4. Conceptual model of contraceptive outcomes included in systematic reviews



Note: *Dashed lines indicate that evidence is lacking on the links between knowledge and method choice and attitudes and method choice. A circular arrow indicates that adherence and continuation over time must both occur over time to confer protection from unintended pregnancy.*

1.B.4.b Contraceptive knowledge

As summarized in Table 1-1, the majority of the studies found that interventions (overall, 6 of 8) had a significant impact on participants' knowledge of contraceptive methods; however, few

studies have shown that an increased level of contraceptive knowledge translates into contraceptive behavior [79, 120]. Studies have found that contraceptive knowledge does not predict contraceptive choice or use [66, 121-124]. Contraceptive knowledge is not included as an outcome in the present research.

1.B.4.c Contraceptive attitudes

Similarly, evidence of the impact of interventions on attitudes about contraception – and, in turn, the impact on contraceptive choice or use – is lacking. The only study in the systematic reviews that explicitly examined attitudes [123] did not find a positive association between contraceptive use and the attitudes studied (attitudes about becoming pregnant, perceived partner attitudes, and attitudes about specific contraceptive methods). Other systematic reviews examining the link between contraceptive attitudes and contraceptive choice or use have yielded mixed evidence, because influences on contraceptive use are complex and multifactorial [21, 125-128]. Contraceptive attitudes are not included as outcomes in the current dissertation research.

1.B.4.d Contraceptive method choice

As shown in Figure 1-4, contraceptive method choice is the initial outcome upon which each of the other behavioral contraceptive outcomes is predicated. Yet only 5 of the studies in the systematic reviews examined contraceptive method choice, and only one intervention – a Nigeria-based study of an intervention for pregnant women with 4 counseling sessions conducted over the course of pregnancy – was found to have a significant impact on method choice [104]. A more recent intervention not included in the systematic reviews summarized in Table 1-1, a randomized controlled trial conducted among 222 post-abortion clients in New York City [129], tested the efficacy of the World Health Organization's Decisionmaking Tool for Family Planning Patients [102, 130] and found no significant difference in choice of a very effective method (<1% failure rate in 1 year, typical use).

1.B.4.e Contraceptive method use at sex, adherence, and continuation

Contraceptive method use, adherence, and continuation – outcomes that encompass a wide range of behaviors that can be complex to measure [116] – were the most commonly examined outcomes in the body of literature. Overall, 13 of the 42 studies that examined any contraceptive use outcome found a significant impact from the studied interventions. But the only review to conduct meta-analyses, including findings from 22 different randomized trials in the United States, United Kingdom and Canada, published from 1970 through 2000 [92], found no significant impact of any of the types of interventions studied – school-based sex education, abstinence programs, multifaceted programs, or family planning clinic-based education and counseling – on initiation of sexual intercourse, use of birth control at every intercourse or use of birth control at last intercourse.

1.B.4.f Pregnancy rates

Overall, 12 of the interventions included pregnancy rates among intervention participants as an outcome, and of these, 4 showed significant impact. The successful interventions included a study of contingency counseling among 914 family planning patients (which found a reduction in unintended pregnancy rates at 6 months but not at 12 months) [100]; a high-intensity developmentally-based intervention among school-age girls that also focused on academic achievement [94]; a home-visiting intervention with biweekly sessions for African-American teen mothers [112]; and an intervention that included both African-American teens and their parents [113].

Other studies focused on pregnancy among the partners of male intervention participants. One intervention, the Postponing Sexual Involvement project, a school-based abstinence intervention in California, found significant reductions in pregnancy rates among the

partners of male participants. Pooled analyses conducted by DiCenso et al. [92] also found a positive effect on pregnancy rates among female partners of male participants in interventions on delaying sexual initiation [92, 95].

1.B.5 Limitations of Evidence Base

1.B.5.a Quality of existing data

Regardless of the outcome studied, in total, less than one-fourth of the 72 interventions included in these systematic reviews found a positive impact on contraceptive knowledge, attitude, or behavior outcomes. Many of the studies that did find a significant impact examined knowledge outcomes, which has not consistently been found to predict contraceptive method choice or use. With the exception of intensity of intervention – discussed below (1.B.5.b.) – no pattern emerged in terms of setting (school-based or clinical), format (one-on-one or group) outcome, or theoretical model that resulted in more consistent impact than another. In the review of theory-based interventions [82, 83], for instance, the majority of the theory-based interventions (10 of 14) had at least one positive impact, but no single underlying theory was found to consistently result in significant impact.

Small sample size with insufficient statistical power was the most commonly cited reason for lack of positive findings. Recognizing insufficient power as a barrier, the current dissertation research was designed with a large sample size, with almost 2,500 family planning patients.

All of the systematic reviews of contraceptive interventions cited the lack of high-quality evidence, notably randomized controlled trials. Two of the Cochrane reviews [81, 83] included quality ratings using standard measures [131]; of the 22 studies examined, only 3 were of high quality, 9 were moderate, and 10 were of low or very low quality. The most extensive review (with 74 studies included in the evidence review) by Moos and colleagues, noted that “existing

studies suffer from appreciable threats to internal validity and loss-to-follow-up" and concluded that "the quality of the existing research does not provide strong guidance for recommendations about clinical practice, but does suggest directions for future investigations ([79], p.115)." In fact, the Moos review included only 1 randomized controlled trial. The Cochrane review on continuation and adherence, updated in 2011, noted that "most studies to date have shown no benefit of strategies to improve adherence and continuation," but that the trials had "important limitations….[including]….small sample sizes…high losses to follow-up, and the intervention and its intensity varied across the studies (p.5 [81])."

1.B.5.b Intensity of interventions

The varied intensity of interventions included in the systematic reviews limited authors' ability to conduct pooled analyses of the studies with small sample sizes [81]. But patterns in the findings among the varied intensities of interventions were evident. In the systematic review of RCTs conducted 1970 through 2000 [92], positive effects on behavior were only found among those studies with intensive interventions: one, an abstinence program in Los Angeles conducted over 8 sessions found lower rates of pregnancy among intervention participants [132]; the other abstinence program in California included 5 sessions [95]; and another community-based program consisted of a minimum of 21 hours of intervention [51, 133, 134]. The Nigeria-based study included in the 2008 Cochrane review [68], which found increased choice of effective contraceptive methods including sterilization among those in the intervention arm, included 4 intervention sessions over the course of pregnancy [104]. And, the only study to find an increase in condom use in the US Preventive Services Task Force review involved very intensive counseling, with 8 2-hour sessions delivered over 8 weeks, followed by a 2-hour booster session delivered about 7 months after completion of the intervention [101].

There were few statistically significant findings among studies that tested single-session interventions. The two single-session interventions that found significant changes in contraceptive behavior were limited in scope and population. The study that found increased rates of continuation among Depo-Provera users after 12 months was conducted only among women who had chosen the specific method; the counseling was not related to any other contraceptive methods [115]. The other single-session intervention, which found an increase in use of effective contraception, was a theory-based intervention conducted only among college students who were at risk of alcohol-exposed pregnancies due to binge drinking [108]. A potential limitation of single-session contraceptive interventions, cited by several authors, is that the intensity of an experimental intervention may not offer value added beyond the routine counseling provided by the family planning provider [129, 135].

1.B.6 Populations included in interventions

Despite documented socioeconomic disparities in unintended pregnancy [2, 3], only one intervention studied, a flipchart for communicating contraceptive effectiveness [130], was specifically designed to reach populations with low educational attainment or with low functional health literacy skills [120, 136-139]. Of the US-based interventions with statistically significant impact listed in Table 1-1, only one, the contingency counseling intervention conducted in the 1980s [100] was developed in Spanish. Two more recent interventions – one using a modified version of the flipchart [129] and the other using telephone reminders [135] – were developed in both Spanish and English, but did not find statistically significant impact on the outcomes studied.

1.C INNOVATION

The dissertation research was developed to address these gaps in the evidence, in terms of the type of intervention, the unique study population, and the overall study design and sample size.

The intervention incorporates features that set it apart from the interventions that have already been developed and tested. First, it is a computer-based intervention; such interventions ensure fidelity of implementation (the way treatment is delivered [140]), ensure standardization of the messages used, and require little training or staff input to implement or replicate. Interventions using audio-computer-assisted self-interviewing (ACASI) targeting other health outcomes have been found to be an effective modality for low literacy populations [141, 142]. Yet of all of the interventions included in the systematic reviews that examined contraceptive behavior outcomes, only two were computer-based [143, 144], and neither found a significant impact on the outcomes studied. The intervention designed and tested in this dissertation research is low-intensity, requiring only a single session.

Filling a gap in terms of populations reached, the intervention is available in both Spanish and English and incorporates audio-computer assisted self-interviewing (ACASI) technology so that no reading is required to engage in the intervention. The outcomes examined – contraceptive method choice (an outcome studied by only 5 of the trials included in the systematic review in Table 1-1), continuation and adherence – are closely linked to the long-term goal of reducing unintended pregnancy.

Finally, the intervention was tested in a randomized controlled trial with large sample size. Using a large-scale randomized controlled trial, which by design addresses both measured and unmeasured confounding, improves both validity and precision, thus responding to calls for high-quality research.

1.D SCOPE OF THE DISSERTATION

Recognizing the need for high-quality research testing the impact of contraceptive counseling or assessment interventions on contraceptive method choice, a three-arm randomized controlled

trial to test the efficacy of a computer-based contraceptive assessment module in increasing the proportion of patients choosing an effective method of contraception was conducted among almost 2,500 family planning patients at two federally-funded family planning centers in a shared clinical network in New York City. Table 1-2 summarizes the three randomization arms.

Table 1-2. Summary of randomization arms

Randomization arm	Module use	Materials
Intervention + Tailored	Complete assessment module	Tailored health materials based on responses to module
Intervention + Generic	Complete assessment module	Generic health materials listing methods available at center
Control	No module – only 10 demographic questions	Generic health materials listing methods available at center

In this dissertation, the development and validation of the bilingual (Spanish/English) computer-based contraceptive assessment module tested in the randomized controlled trial is described. The impact of the intervention on contraceptive method choice at the time of provider visit (Chapter 2) is quantified through intent-to-treat analyses (among all who were randomized) and as-treated analyses (among those who completed the intervention and data collection procedures on the day of their family planning visit) using several sources of outcome data. The contraceptive preferences, priorities, and choices of family planning patients in the study, and the impact of individually tailored materials on contraceptive choice (Chapter 3) are described. The impact of the intervention on contraceptive method use, continuation, and adherence (correct and consistent use of method) 4 months after the family planning visit (Chapter 4) in a randomly-selected subsample is quantified. Finally, the implications of the findings, potential next steps, and the public health significance of the research are discussed (Chapter 5). The results of supplementary analyses examining possible sources of bias are presented in Appendices.

1.D.1 Specific Aims

Analyses as part of the dissertation examine the following hypothesis-driven specific aims in the three-armed randomized controlled trial among family planning patients. The three-arm design was developed to enable testing the effect of the assessment module (Specific Aim 1) separately from the effect of tailored educational materials (Specific Aim 2).

Specific Aim 1: Assess the impact of a computer-based contraceptive assessment module on choice of an effective contraceptive method

Primary Outcome for Specific Aim 1: Choice of an effective contraceptive method on the day of visit. An effective method is one with fewer than 10 pregnancies per 100 women in one year of typical use [7] [See Table A1-1].

Hypothesis 1a: In intent-to-treat analyses using clinical-administrative data on contraceptive method choice, Intervention + Tailored participants and Intervention + Generic participants, compared to Control participants, will be more likely to choose an effective contraceptive method.

Hypothesis 1b: In as-treated analyses using clinical-administrative data on contraceptive method choice, Intervention + Tailored participants and Intervention + Generic participants, compared to Control participants, will be more likely to choose an effective contraceptive method.

Hypothesis 1c: In as-treated analyses using self-report data on contraceptive method choice, Intervention + Tailored participants and Intervention + Generic participants, compared to Control participants, will be more likely to choose an effective contraceptive method.

Main analyses and findings for Specific Aim 1 are included in Chapter 2; data collection procedures for Specific Aim 1 are reviewed in Appendix 1; and supporting analyses are included in Appendix 3.

Specific Aim 2: Assess the impact of individually tailored health materials on choice of a "best fit" contraceptive method

Primary Outcome for Specific Aim 2: Choice of a "best fit" contraceptive method on the day of visit. A "best fit" method is one identified by the module as being both effective and acceptable given participant responses to the questions in the module [See Table A3-1].

Hypothesis 2a: Intervention + Tailored participants, compared to Intervention + Generic participants, will be more likely to choose a "best fit" contraceptive method.

Main analyses and findings for Specific Aim 2 are included in Chapter 3; data collection procedures for Specific Aim 2 are reviewed in Appendix 1; and supporting analyses are included in Appendix 3.

Specific Aim 3: In a subsample of participants randomly selected for follow-up (n=269), assess the impact of the contraceptive assessment module on contraceptive method use and continuation 4 months after family planning visit

Primary Outcome for Hypothesis 3a: Use of any effective contraceptive method 4 months after the family planning visit. An effective method is one with fewer than 10 pregnancies per 100 women in one year of typical use [7] [See Table A5-1].

Hypothesis 3a: Intervention + Tailored participants and Intervention + Generic participants, compared to Control participants, will be more likely to use any effective contraceptive method 4 months after the family planning visit.

Primary Outcome for Hypothesis 3b: Continued use of the same contraceptive method chosen at the family planning visit 4 months earlier, regardless of method effectiveness.

Hypothesis 3b: Intervention + Tailored participants and Intervention + Generic participants, compared to Control participants, will be more likely to continue use of the same contraceptive method chosen at the family planning visit 4 months earlier.

Main analyses and findings for Specific Aim 3 are included in Chapter 4; data collection procedures for Specific Aim 1 are reviewed in Appendix 4; and supporting analyses are included in Appendix 5.

Table 1-3 summarizes the hypotheses, primary outcome variables, sample sizes, and comparisons for each of the specific aims and hypotheses.

Table 1-3. Summary of analyses included in dissertation

Hypothesis	Description of analysis	Outcome	Source of outcome data	N	Sample	Comparisons
Specific Aim 1: Assess the impact of a computer-based contraceptive assessment module on choice of an effective contraceptive method						
1a	Intent-to-treat analysis	Chose an effective method of contraception on day of visit	Clinical-administrative data	2,448	All patients who were randomized	Intervention + Tailored Intervention + Generic Control [Ref.]
1b	As-treated analysis	Chose an effective method of contraception on day of visit	Clinical-administrative data	1,983	Patients who completed participation in the intervention or control condition and data collection on day of visit (subset of 1a)	
1c	As-treated analysis	Chose an effective method of contraception on day of visit	Patient self-report data			
Specific Aim 2: Assess the impact of individually tailored health materials on choice of a "best fit" contraceptive method						
2a	As-treated analysis among module users	Choice of a method ranked as a "best fit" by the module	Patient self-report data; module ranking	1,454	Intervention + Tailored and Intervention + Generic participants for whom the module identified at least one "best fit" method (subset of 1b/1c)	Intervention + Tailored Intervention + Generic [Ref.]

Table 1-3, Continued

Hypothesis	Description of analysis	Outcome	Source of outcome data	N	Sample	Comparisons
Specific Aim 3: In a subsample randomly selected for follow-up (n=269), assess the impact of the contraceptive assessment module on contraceptive method use and continuation 4 months after family planning visit						
3a	Follow-up analysis of contraceptive use	Used any effective method of contraception 4 months after visit	Follow-up survey	269	Patients who completed follow-up survey (subset randomly selected from 1b/1c)	Intervention + Tailored Intervention + Generic Control [Ref.]
3b	Follow-up analysis of contraceptive continuation	Continued use of contraceptive method chosen at visit, 4 months later	Follow-up survey	224	Patients who completed follow-up survey and who had chosen any method on the day of visit (subset of 3a)	

2 CHAPTER 2: IMPACT OF CONTRACEPTIVE ASSESSMENT MODULE ON METHOD CHOICE (SPECIFIC AIM 1)

2.A INTRODUCTION

Despite documented socioeconomic disparities in unintended pregnancy [2, 3], the established link between socioeconomic status and literacy skill level [136], and the fact that there are 47 million women in the United States with limited literacy skills [145], few interventions [69, 102, 129, 130] have been specifically designed to reach populations with low educational attainment or with low functional health literacy skills [120, 136-139]. Many studies of interventions to improve contraceptive assessment and counseling have lacked internal validity, either because of confounding or loss-to-follow-up [79], and most have been statistically underpowered [107, 129]. Interventions that have been found to have a significant impact on contraceptive method choice are intensive, occurring over multiple sessions, limiting opportunities to translate them at the population level [68, 81].

To address the lack of structured interventions, particularly for women with low functional literacy skills or low educational attainment, a contraceptive choice algorithm [146] was adapted into a module incorporating audio-computer assisted self-interviewing (ACASI) and touchscreen technology. A three-arm randomized controlled trial of the module was conducted in two urban family planning clinics serving low-income Latinas to test its efficacy in increasing the proportion of patients choosing effective contraceptive methods.

2.B MATERIALS AND METHODS

2.B.1 Study Design, Aims & Setting

A three-arm randomized controlled trial to test the efficacy of a computer-based contraceptive assessment module in increasing the proportion of patients choosing an effective method of

contraception was conducted over two years at two federally-funded family planning centers in a shared clinical network in New York City. The three-arm design was used to allow analyses testing the impact of the module separately from the impact of tailored health materials. Participants were randomized to use the computer-based contraceptive assessment module and receive tailored health materials based on their responses to the module (Intervention + Tailored); to use the assessment module and receive generic health materials (Intervention + Generic); or to a control condition (Control) (summarized in Table 1-2).

2.B.2 Participant Recruitment

Family planning patients were approached sequentially as they registered for their appointment, and were screened for eligibility. Participant recruitment began in March 2009 and ended in August 2010; final contacts with patients were completed in January 2011. Patient recruitment activities were carried out by three trained bilingual (Spanish/English) Project Assistants. Participants received a $10 gift card.

English- or Spanish-speaking women age 16 and over, capable of providing informed consent, who had a family planning visit on the date of recruitment were eligible for participation. Walk-in pregnancy test patients and women who spoke neither Spanish nor English were not eligible. Women not at risk for unintended pregnancy – those who were pregnant, seeking pregnancy, had tubal ligation or a current partner with a vasectomy, or reported they were going through or completed menopause – were not eligible. The trial was not registered with the clinicaltrials.gov network. The study protocol was reviewed and approved by the Institutional Review Board (IRB) of Public Health Solutions, and all eligible participants provided written consent. All patient recruitment materials, written below 7th grade reading level, were available in Spanish and English and were read aloud to potential participants by the Project Assistants. Consent included permission to view clinical and administrative data from their visit and permission to be contacted via telephone 4 months later.

2.B.3 Randomization generation, allocation and procedures

Randomization was implemented by computer using a non-deterministic algorithm, determined by the deci-second the participant began the computer-based survey. Block randomization was used: after each 100 participants were randomized, an evaluation procedure determined the balance among the groups achieved by chance and the proportion of participants assigned to each group. If either group contained ±5% of the desired weighting of the randomization allocation, the block of 100 was considered "not balanced,' additional deci-second assignment numbers were allotted to the lesser-recruited group. During the rebalancing phase, participants continued to be randomly assigned to all groups, eliminating the possibility of temporal patterns in assigning all participants to the under-recruited arm. The rebalancing process was monitored as each new participant was randomized and was discontinued when balance was achieved. Allocation was not stratified by age or by center of recruitment.

2.B.4 Intervention Arms

Following screening and consent procedures, participants were given a touchscreen laptop loaded with an audio-computer assisted self-interviewing module. Participants were randomized into one of three arms. Participants in the Intervention + Tailored arm, following interaction with the module, received printed tailored materials listing methods that were a best fit for them given their responses to the module. Methods on the tailored materials were categorized as "Green: These are the birth control methods that fit your life and goals well and prevent pregnancy best;" "Yellow: These birth control methods are either less good at preventing pregnancy or may be a problem for you;" or "Red" for medically contraindicated methods. Participants were instructed to share the materials with the provider during the visit. Participants in the Intervention + Generic arm interacted with the same assessment module, but received a generic handout listing contraceptive methods available at the center. Participants in

the Control arm used the same touchscreen interface to answer 10 basic demographic questions and received the same generic handout. Health materials were generated in Spanish or English, depending on the language used to complete the module or the control survey. In Appendix 1, Figures A1-1 through A1-5, illustrate a sample screen shot, a photo of a user interacting with the module, a sample of a tailored handout, and a sample of the generic handout.

Regardless of the intervention arm to which they were randomized, all study participants used the laptops before their visit with a health care provider. No changes were made to clinical services; all study participants received family planning services according to existing standard of care. At the end of their clinical visit, participants completed an interviewer-administered survey that assessed their satisfaction with the computer module and the contraceptive method chosen (Table A1-3). The results of the patient satisfaction with the use of the computer module are outlined in Appendix 1, Section 6.B.

Randomization allocation was shifted during the course of recruitment to allow for recruitment of a sufficient number of control arm participants in the Control condition. In the first phase of allocation (first 11 months of recruitment), 50% of participants were randomized to the Intervention + Tailored arm, and 50% were randomized to the Intervention + Generic arm. In the second phase of allocation, beginning in February 2010, 70% of participants were randomized to the Control arm and 30% were randomized to the Intervention + Tailored arm. Because some participants received tailored educational materials (Intervention + Tailored) while others received generic materials (Intervention + Generic and Control participants), and were instructed to bring the materials into their provider visit, randomization allocation was not fully blinded to providers. More detailed information on the shift in randomization allocation, as it relates to participant recruitment, and as a potential source of bias, is provided in Appendix 2.

2.B.5 Description of Computer-Based Contraceptive Assessment Module

The intervention included use of a self-administered computer-based module incorporating an algorithm that accounts for patient preferences; medical, obstetric, gynecologic and contraceptive history; and sexual health risk factors. In initial development, the method recommendations generated by the algorithm were tested for validity, compared against a gold standard of expert clinical recommendation [146]. The algorithm integrated the World Health Organization (WHO)'s Medical Eligibility Criteria, with recent updates by the Centers for Disease Control, which provide clinical guidance regarding safe use of contraceptive methods given medical conditions [70, 71]. The algorithm included approximately 50 questions (depending on skip patterns), the responses to which guided underlying calculations on goodness of fit for 19 currently available contraceptive methods. The wording of all of the questions, and response options, is provided in Appendix 1 (Table A1-1). An example of the scoring for combined oral contraceptives conducted by the underlying algorithm is provided in Appendix 1, Section 6.A.2. The underlying scoring incorporated both participants' responses and effectiveness, weighting more effective methods more heavily than less effective methods. The clinical algorithm was translated into Spanish and adapted into a computer module accessible to populations with low literacy or low educational attainment by incorporating audio computer-assisted self interviewing (ACASI) and touchscreen technologies so that participants could interact with the module without any reading or typing required. Headphones were used to listen to the audio. Information on the use of the audio portion of the module is provided in Appendix 1, Section 6.B. Validation testing, using the same sample cases (n=233), was repeated for the ACASI version of the module against clinical recommendations, using both the Spanish and English versions.

2.B.6 Data Collection

Data were collected through self-reported responses to the ACASI module (Table A1-1). Sociodemographic data and provider's report on the contraceptive method chosen at the time of visit were exported from the clinical-administrative database (cf Appendix 1, section 6.A.4.). Following the participant's visit with the provider, interviewers administered a brief survey to participants on satisfaction with their visit and using the computer, and the contraceptive method chosen at their visit. The wording of the questions and response options for the survey conducted at the end of the visit is provided in Table A1-3. Additional analyses on the reliability of independent and dependent variables are reviewed in Appendix 1, Section 6.C.

2.B.7 Primary Outcome: Effectiveness of Contraceptive Method Chosen

Effectiveness of the contraceptive method chosen at the time of the visit was the primary outcome (Table A2-1). The effectiveness of the contraceptive method chosen was dichotomized as: effective methods (those with fewer than 10 pregnancies per 100 women in 1 year of typical use [73, 147]), also referred to as WHO Effectiveness Tier 1 and Tier 2 [102]; and less effective methods (10 or more pregnancies per 100 women in 1 year of typical use) or no method. Contraceptive methods in the effective group include female sterilization, male sterilization (vasectomy), contraceptive implants (Implanon), and intrauterine devices (Mirena and Paragard), injectable contraceptives (Depo-Provera), combined oral contraceptives, progestin only pills, contraceptive ring (NuvaRing), and contraceptive patch (OrthoEvra). Women who reported more than one method were categorized as choosing the method with higher effectiveness, consistent with National Survey of Family Growth (NSFG) methodology [32]. Potential considerations of the operationalization of the primary outcome are discussed in Appendix 2, Section 7.A.

2.B.8 Data Analyses: Statistical Methods

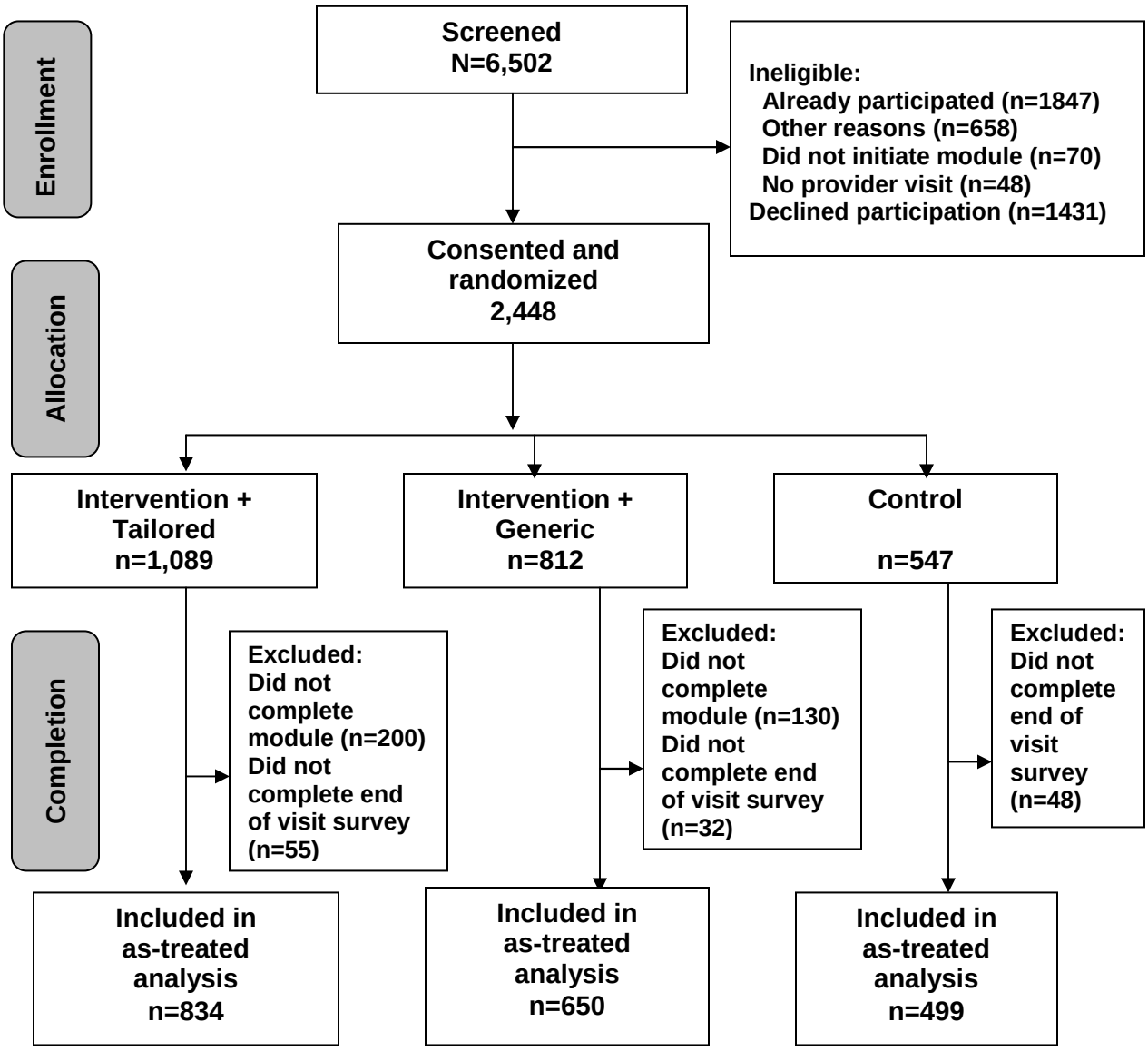
Data analyses were conducted using STATA 10.1 (StataCorp, College Station, TX). Analyses were conducted among all who provided consent (intent-to-treat) and those who completed participation and data collection procedures on the day of their family planning visit (as-treated). Tabular analyses compared characteristics of participants in each arm using ANOVA and Chi-square tests. Distribution of contraceptive method choice was compared across randomization arms using Chi-square tests and binary logistic regression models comparing each intervention arm to the control arm, unstratified and stratified by clinical site. To assess missing data as a source of information bias, intent-to-treat analyses were subjected to sensitivity analyses, under conservative assumptions about the distribution of missing outcome data in the clinical-administrative database (n=190). Additional information about the assumptions underlying the sensitivity analyses is provided in Appendix 2, Section 7.C.5.

2.C RESULTS

2.C.1 Enrollment

As shown in Figure 2-1, a total of 6,502 women were screened for participation in the study over the 18-month course of recruitment. Of these, 1,847 (28%) were ineligible because they had already participated at a prior visit, 658 were ineligible for other reasons (10%), 1,431 (22%) declined participation, 70 (1%) began the consent process but did not initiate the module, and 48 did not have a provider visit on the day of recruitment (<1%), yielding 2,448 women who consented to participate and were randomized (included in intent-to-treat analyses). Of these, 465 did not complete the entire module or the end-of-visit survey, leaving a final sample size of 1,983 available for as-treated analyses. The characteristics of women who declined to participate in the project are discussed in Appendix 1, Section 6.C.3.

Figure 2-1. Flowchart of participant enrollment, allocation, completion and inclusion in analysis.



Participants who completed participation and data collection procedures on the day of their visit and who were included in the as-treated analyses (n=1,983) and those who did not complete participation (n=465) differed significantly by sociodemographic characteristics: women who did not complete participation were significantly more likely to have lower educational attainment, to have used the Spanish version of the module, and to be foreign-born (all Chi-square tests $p<0.001$). Non-completers were also significantly less likely to be in the control group because the number of questions asked using the ACASI module differed by randomization arm (approximately 50 questions for those in Intervention + Tailored and Intervention + Generic groups, compared to 10 questions for those in the Control condition). The most common reasons for not completing use of the module were getting called in to see the provider (50%), having the appointment with the provider rescheduled (20%), technical problems with the ACASI module (10%), and the patient not wishing to continue (10%). The median time to complete the module (among those in the Intervention arms) was 15.2 minutes (mean time 16.5 minutes, sd=8).

As shown in Table 2-1, no significant differences in baseline sociodemographic characteristics were found across randomization arms, but the clinical site of recruitment differed significantly, with 45% of controls recruited at site 1 and 55% at site 2 ($p<0.001$). The 1,983 participants in the as-treated analyses were predominantly Latina (69%), and foreign-born (76%). More than half of participants (56%) chose to use the module in Spanish. Almost all (98%) had incomes below 200% of the federal poverty line, and less than 1% had private insurance.

Table 2-1. Sociodemographic characteristics of as-treated study sample, by randomization arm (n=1,983)

	Intervention + Tailored (n=834)		**Intervention + Generic (n=650)**		**Control (n=499)**		**Total (n=1,983)**		**Test of difference across arms (p)**
Characteristic	**Mean (sd)**		**Mean (sd)**		**Mean (sd)**		**Mean (sd)**		**ANOVA**
Age in years, mean (sd)	27.9 (7.0)		27.8 (7.4)		27.3 (7.1)		27.7 (7.2)		0.279
Weight in pounds, mean (sd)	145.9 (33.0)		142.2 (31.3)		144.0 (31.0)		144.2 (32.0)		0.094
	n	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**Chi-square**
Age category									0.073
16-19	117	(14.0)	103	(15.8)	71	(14.2)	291	(14.7)	
20-24	168	(20.1)	143	(22.0)	121	(24.2)	432	(21.8)	
25-29	205	(24.6)	146	(22.5)	143	(28.7)	494	(24.9)	
30-34	187	(22.4)	125	(19.2)	77	(15.4)	389	(19.6)	
35-39	104	(12.5)	87	(13.4)	58	(11.6)	249	(12.6)	
40 and older	53	(6.4)	46	(7.1)	29	(5.8)	128	(6.5)	
Race/Ethnicity									0.278
Latina, any race	577	(69.2)	461	(70.9)	322	(64.5)	1360	(68.6)	
Non-Latina black	109	(13.1)	79	(12.2)	80	(16.0)	268	(13.5)	
Non-Latina, non-black	134	(16.1)	104	(16.0)	89	(17.8)	327	(16.5)	
Missing or not answered	14	(1.7)	6	(0.9)	8	(1.6)	28	(1.4)	
Preferred module language									0.690
English	368	(44.1)	282	(43.4)	229	(45.9)	879	(44.3)	
Spanish	466	(55.9)	368	(56.6)	270	(54.1)	1104	(55.7)	
Birthplace									0.135
US	205	(24.8)	143	(22.1)	135	(27.2)	483	(24.5)	
Other countries	623	(75.2)	505	(77.9)	362	(72.8)	1490	(75.5)	
Insurance and income status									0.314
None/self-pay <100%FPL	392	(48.5)	325	(51.4)	228	(47.0)	945	(49.0)	
None/self-pay 100-149% FPL	62	(7.7)	43	(6.8)	53	(10.9)	158	(8.2)	
None/self-pay over 150% FPL	18	(2.2)	9	(1.4)	6	(1.2)	33	(1.7)	
Medicaid or other income-eligible public insurance	329	(40.1)	252	(39.9)	194	(39.9)	775	(40.2)	
Private insurance or HMO	8	(1.0)	3	(0.5)	5	(1.0)	16	(0.8)	

Table 2-1, Continued

	Intervention + Tailored (n=834)		Intervention + Generic (n=650)		Control (n=499)		Total (n=1,983)		Test of difference across arms (p)
Characteristic	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**Chi-square**
Clinical site of recruitment									<0.001
Site 1	520	(62.4)	429	(66.0)	227	(45.5)	1176	(59.3)	
Site 2	314	(37.6)	221	(34.0)	272	(54.5)	807	(40.7)	
Educational attainment									0.502
Less than high school	219	(26.6)	180	(28.0)	127	(26.0)	526	(26.9)	
High school graduate/GED	328	(39.9)	249	(38.7)	211	(43.2)	788	(40.3)	
Some college/2-year degree	212	(25.8)	161	(25.1)	113	(23.2)	486	(24.9)	
4 years college or more	63	(7.7)	53	(8.2)	37	(7.6)	153	(7.8)	
Frequency of computer use									0.202
Never	138	(16.6)	94	(14.5)	71	(14.3)	303	(15.3)	
Less than once/month	44	(5.3)	26	(4.0)	14	(2.8)	84	(4.2)	
1-3 times/month	61	(7.3)	42	(6.5)	37	(7.4)	140	(7.1)	
Once/week	76	(9.1)	82	(12.6)	47	(9.4)	205	(10.4)	
Several times/week	169	(20.3)	137	(21.1)	101	(20.3)	407	(20.6)	
Every day	344	(41.3)	268	(41.3)	228	(45.8)	840	(42.4)	

2.C.2 Study Findings: Contraceptive Method Choice

Intent-to-treat analyses were conducted using logistic regression, comparing the proportion choosing an effective contraceptive method (using clinical-administrative outcome data) across randomization arms, including all participants who provided informed consent maintaining randomization assignment (n=2,231 of the 2,448 had available outcome data and were not listed as choosing abstinence). Those randomized to the Intervention + Tailored and Intervention + Generic groups were significantly more likely to choose an effective contraceptive method, compared to those in the control group [Table 2-2a]. The intent-to-treat analyses were repeated using relative risk regression (using log-binomial link) to account for the fact that odds ratios can overestimate risk when the outcome event is common [148, 149]. As would be

expected, the point estimates and confidence intervals for the relative risks were smaller than those for the odds ratios [Table 2-2].

Table 2-2. Intent-to-treat logistic regression and relative risk regression models of choosing an effective contraceptive method, comparing each intervention arm to control condition, adjusted for site of recruitment

	Intent-to-treat, clinical-administrative outcome data n=2,231			
Randomization arm	**n**	**Chose an effective method**		
		%	**OR (95%CI)**	**RR (95%CI)**
Intervention + Tailored	985	75%	1.56 (1.23-1.98) p<0.001	1.14 (1.06-1.23) p=0.001
Intervention + Generic	756	78%	1.74 (1.35-2.25) p<0.001	1.17 (1.09-1.27) p<0.001
Control [Ref.]	490	65%	---	---

Note: *Adjusted for clinical site of recruitment. Effective method is one with fewer than 10 pregnancies per 100 women in 12 months typical use. Patients who reported choosing abstinence were excluded because no typical-use effectiveness data are available: 27 in intent-to-treat; 1 in as-treated patient report; 26 in as-treated, clinical-administrative report.*

Intent-to-treat logistic regression findings were subjected to sensitivity analyses under conservative assumptions about missing outcome data from the clinical-administrative database (n=190, 7.7% of the sample). Among Intervention+ Tailored and Intervention + Generic participants with missing data, the proportion with the primary outcome was assumed to be 10 percentage points lower than in the available data (68% of n=93 and 65% of n=50, respectively), while among Control participants with missing data (n=47), the primary outcome was assumed to be 10 percentage points higher than in the available data (75%), and all participants who were reported to have chosen abstinence (n=27) were assumed to have chosen no method. In these sensitivity analyses, adjusting for recruitment site, patients who used the module were significantly more likely to choose an effective method than those in the control arm: 74% among Intervention + Tailored [AOR= 1.40(95%CI: 1.11-1.75)] and 76% among Intervention + Generic [AOR=1.58 (95%CI:1.24-2.02)], compared to 67% in the control condition.

Tests of statistical interaction between the intervention and language of the module, age group (age 16-24 versus age 25 and over), birthplace, clinical site of recruitment, and contraceptive use status at the start of the family planning visit were conducted among the intent-to-treat sample using relative risk regression [Appendix 2, Section 7.D.1.]. These tests did not achieve statistical significance (with alpha set at 0.05), but the finding for contraceptive use status was of borderline statistical significance (p-value for interaction term p=0.056).

As-treated analyses were conducted among the 1,983 participants who completed the intervention or control condition and all data collection procedures on the day of their visit, using two different sources of outcome data (patient self-report and the clinical-administrative database). As shown in Table 2-3, the results of as-treated analyses were consistent with intent-to-treat analyses (Table 2-2). Family planning patients who used the module (Intervention + Tailored and Intervention + Generic arm participants) were significantly more likely than those in the Control arm to choose an effective method of contraception. These findings were confirmed in as-treated analyses among only participants who were using no method of contraception at the start of the visit (Appendix 2, Section 7.B.3).

Table 2-3. As-treated logistic regression models of choosing an effective contraceptive method, comparing each intervention arm to control condition, by data source, adjusted for site of recruitment

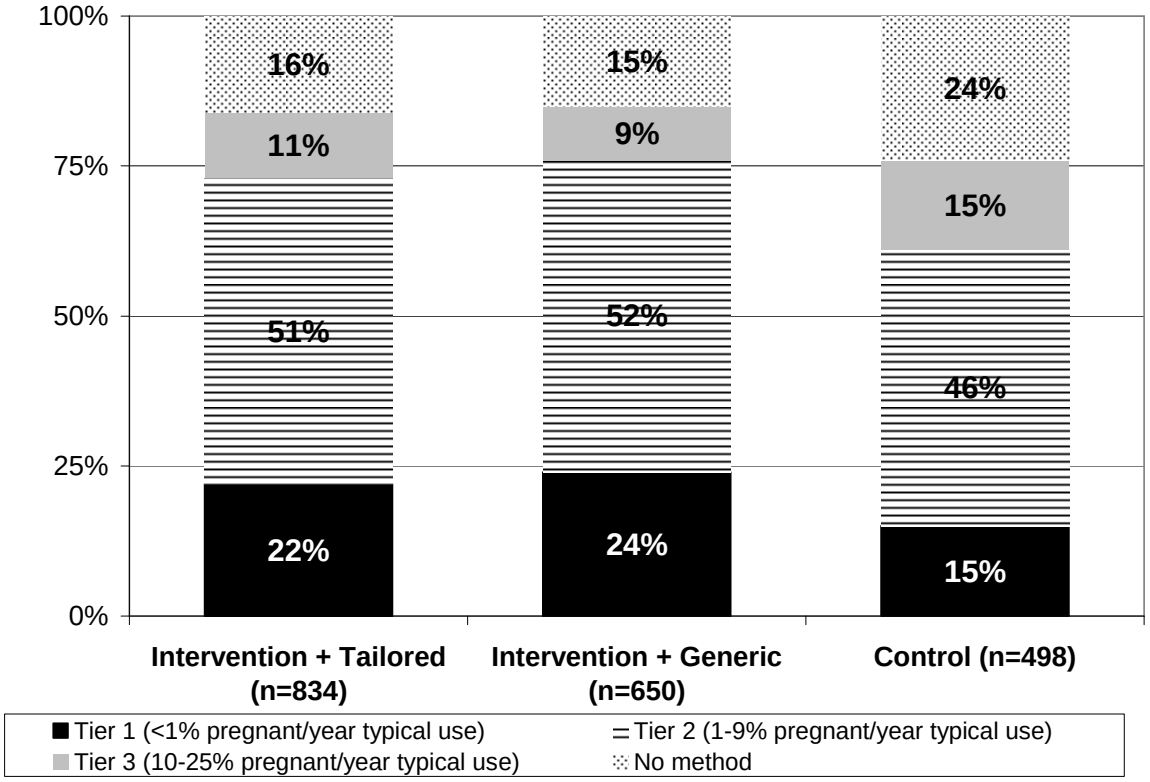
	As-treated, patient self-report outcome data n=1,982			**As-treated, clinical-administrative outcome data n=1,934**		
Randomization arm	**n**	**Chose effective method**		**n**	**Chose effective method**	
		%	**OR (95%CI)**		**%**	**OR (95%CI)**
Intervention + Tailored	815	76%	1.55 (1.21-1.99) p=0.001	834	73%	1.63 (1.28-2.07) p<0.001
Intervention + Generic	637	76%	1.56 (1.21-2.04) p=0.001	650	76%	1.86 (1.44-2.41) p<0.001
Control [Ref.]	482	66%	---	499	61%	---

Note: *Adjusted for clinical site of recruitment. Effective method is one with fewer than 10 pregnancies per 100 women in 12 months typical use. Patients who reported choosing abstinence were excluded because no typical-use effectiveness data are available: 27 in intent-to-treat; 1 in as-treated patient report; 26 in as-treated, clinical-administrative report.*

The as-treated logistic regression models using participant self-report outcome data were repeated among the subset of participants who reported that they were not using contraception at the start of their visit (n=888). Participants who used the module were significantly more likely to choose an effective method: 60% among those who received tailored materials [Intervention + Tailored AOR=1.64 (95% CI: 1.18-2.29] and 63% among those who received generic materials [Intervention + Generic AOR=1.87 (95% CI: 1.31-2.68)], compared to 47% among control arm participants. Additional results of subgroup analyses are presented in Appendix 2, Section 7.B.3.

As-treated analyses using the participant's self-report were repeated using a categorical operationalization of contraceptive method choice on the day of visit. As shown in Figure 2-2, participants in the Intervention + Tailored and Intervention + Generic arms were significantly (Chi-square test $p<0.001$) more likely to choose methods in the top effectiveness tier (all but one participant chose IUDs, with one choosing vasectomy), and less likely to choose no method, compared to those in the control group. The specific methods included in each effectiveness tier are listed in Appendix 2, Section 7.C.

Figure 2-2. Proportion of patients in as-treated sample choosing contraceptive methods in each effectiveness tier, by randomization arm (n=1,982)



Note: *Chi-square test of difference across randomization arms p<0.001. Unstratified by clinical site. Only one participant who chose a Tier 1 method chose vasectomy; all others in Tier 1 chose IUDs.*

Finally, as-treated analyses using participants' self-report outcome data were repeated operationalizing contraceptive method choice on the day of visit as a dichotomous variable any/none. Participants who used the module were significantly more likely to choose any contraceptive method: 84% among those who received tailored materials [Intervention + Tailored AOR=1.52 (95% CI: 1.15-2.01] and 85% among those who received generic materials [Intervention + Generic AOR=1.60 (95% CI: 1.18-2.17)], compared to 76% among control arm participants. The specific contraceptive methods chosen among participants in the as-treated

sample in each randomization arm, both as a whole and the subset who were using no method of contraception at the start of their family planning visit, are presented in Appendix 2, Section 7.B.2.

2.D DISCUSSION

In a randomized controlled trial, women who used a self-guided computer-based assessment module were significantly more likely than women assigned to a control group to choose an effective method of contraception (with 10 or fewer pregnancies among 100 women in one year of typical use) at the time of their visit. The intervention ensures standardization of high-quality contraceptive assessment [150] while incorporating the preferences of the individual patient. Our findings support prior research that suggested that patient-centered counseling can influence contraceptive method choice [33, 74-78], addressing documented disparities in family planning outcomes [34, 151, 152]. In contrast to previous studies of tailored health materials [153], this study found that the tailored health materials were no more effective than generic materials in changing contraceptive choice.

The study had some limitations, many of which were mitigated through additional analyses to assess sources and directions of potential bias. Of the 2,448 family planning patients who provided consent to participate, 465 did not complete participation (ACASI module and end-of-visit survey), and these women were more likely to be Spanish-speaking, foreign-born, and with low educational attainment. Results from intent-to-treat analyses, however, did not differ from the as-treated analyses among those who completed the module or control condition, suggesting that selection bias due to non-completion would not explain the findings. Supporting analyses of the impact of non-completion on the day of the family planning visit are reviewed in Appendix 2, Section 7.B.4.

Missing outcome data from the clinical-administrative database, while high (7.7% of the intent-to-treat sample), was also not a source of bias: sensitivity analyses under conservative

assumptions still revealed significant associations. Additional information on the sensitivity analyses conducted is provided in Appendix 2, Section 7.C.5.

Information bias that may have resulted from systematic or random errors in the clinical-administrative database, or from systematic errors in participant self-report of outcome data, was not an alternative explanation for the intent-to-treat findings. As-treated analyses were conducted using the two different outcome data sources, and, as shown in Table 2-2, the proportion of patients who reported choosing an effective method was lower using the self-report data compared to the clinical-administrative data. Both models, however, remained statistically significant. Additional information on the discrepancies between self-report and clinical-administrative outcome data is provided in Appendix 1, Section 6.C.

Due to a shift in randomization allocation in the later stages of recruitment to allow recruitment of sufficient number of participants into the control arm, and a result of the fact that randomization was not stratified by site, randomization across arms was not equal at the two participating clinical sites. This imbalance required analyses to be stratified by site, resulting in lowered statistical power.

Controls were more likely to be recruited later in the 18-month recruitment period, introducing the possibility of time-related confounding. This would bias findings toward the null, as controls had greater access to effective methods in later time periods [154, 155]. Prescribing patterns within the clinical network (including 4 sites not participating in the trial) revealed that prescribing of highly effective methods was higher in the time period in which most controls were recruited than in the earlier time period. Supporting analyses of potential confounding by time or clinical recruitment site, introduced by the shift in randomization, is discussed in Appendix 2, Section 7.C.1 and 7.C.2.

The study was not blinded: patients were instructed to bring their tailored materials into their visit. It is possible that the provider could be more likely to counsel patients with tailored

materials more thoroughly about effective contraceptive methods. However, bias due to the lack of provider blinding to intervention arm status would not explain the observed differences between the Intervention + Generic and Control groups, both of whom received generic output.

Finally, the study was conducted among a population of primarily foreign-born, low-income family planning patients; the findings therefore may not be generalizable to other populations or clinical settings. As discussed in greater detail in Appendix 2, Section 7.E., the centers at which the trial was conducted receive funding to make effective contraceptive methods more available; as a result, the proportion of patients at the centers choosing effective methods is higher than at other federally-funded family planning centers. This would not, however, explain the observed differences in contraceptive method choice between the Control arm and those in the Intervention + Tailored and Intervention + Generic arms. The potential lower generalizability of the findings is offset by the fact that the intervention directly responds to the needs of women with low educational attainment [136-139, 156-158] and Spanish-speaking Latinas [159], both groups at increased risk of unintended pregnancy.

The findings were robust, and held up in analyses using both self-report and clinical-administrative outcome data, in sensitivity analyses, and in both intent-to-treat and as-treated analyses. Half of unintended pregnancies could be averted if effective contraceptive methods were used [160]. The impact of this intervention on meeting this long-term goal, as discussed in Chapter 5, merits further examination.

3 CHAPTER 3: IMPACT OF TAILORED MATERIALS ON CHOICE OF A "BEST FIT" CONTRACEPTIVE METHOD (SPECIFIC AIM 2)

3.A INTRODUCTION

Research has revealed discrepancies between childbearing intentions and contraceptive use [161-163]. More than half (53%) of women who gave birth in the US in 2004 and who reported they were not trying to become pregnant were not using any contraception pre-pregnancy [11]. Sociodemographic differences in contraceptive choice and use mirror those in unintended pregnancy [32]. Individual sociodemographic characteristics, however, are not necessarily the most salient predictors of contraceptive choice and use. Numerous studies have found that an individual's contraceptive history, preferences and priorities – including concerns about side effects [162, 164-166], relationship status [167-169], and ambivalence about childbearing intentions [170, 171] – were strong predictors of contraceptive behavior, even after adjustment for sociodemographic characteristics [163, 172]. Because use of contraceptive methods that are not acceptable increases the likelihood of discontinuation or inconsistent use, thus increasing the risk of unintended pregnancy [172], the literature has suggested that providing patient-centered contraceptive counseling addressing individual preferences and priorities may address documented disparities in family planning outcomes [34, 151, 152].

While there exists a strong body of research on socioeconomic, racial and ethnic, and other demographic factors in contraceptive use [2, 34, 38, 61, 63, 64, 173], there has been far less research on the role of individual, personal factors in contraceptive decisionmaking, [122, 174, 175] particularly among Latinas [159, 176, 177]. Here, the contraceptive preferences and priorities of family planning patients who used a computer-based contraceptive assessment module in the context of a randomized controlled trial – predominantly low-income Latina

women – are described, and the extent of agreement between the stated preferences, priorities and histories and contraceptive method choice is assessed.

3.B MATERIALS AND METHODS

3.B.1 Study Design, Aims & Setting

A three-arm randomized controlled trial testing the efficacy of a computer-based contraceptive assessment module in increasing the proportion of patients who chose an effective method of contraception was conducted at two family planning centers in a shared clinical network in New York City. Participants were randomized to: 1) use the computer-based contraceptive assessment module and receive tailored health materials based on their responses to the module (Intervention + Tailored); 2) use the assessment module and receive generic health materials (Intervention + Generic); or 3) a control condition (Control), as summarized in Table 1-2. Assessment of the primary outcome for this analysis relies on the responses to the full assessment module; therefore, Control group participants have been excluded from these analyses.

3.B.2 Participant Recruitment

Participant recruitment was conducted by three trained bilingual (Spanish/English) Project Assistants from March 2009 through August 2010. Patients were approached sequentially as they registered for a family planning appointment and screened for eligibility. English- or Spanish-speaking women age 16 and over, capable of providing informed consent, who presented at the recruitment sites for a family planning visit were eligible. Women who were pregnant, seeking pregnancy, who had tubal ligation or a current partner with a vasectomy, or who reported they were going through or completed menopause were not eligible. The study protocol was approved by the Institutional Review Board (IRB) of Public Health Solutions. All eligible participants provided written consent, and received a $10 gift card at the time of their

visit. Informed consent included permission to view clinical and administrative data from the family planning visit.

3.B.3 Intervention Arms

The contraceptive assessment module included a series of approximately 50 questions about preferences and priorities; medical, obstetric, gynecologic and contraceptive history; and sexual health risk factors, using a touchscreen computer interface programmed with audio computer-assisted self interviewing (ACASI) technology in both English and Spanish [146, 178]. A validated underlying algorithm ranked contraceptive methods in terms of effectiveness and acceptability given the participant's responses to the questions [146].

Participants in the Intervention + Tailored arm, after interaction with the module, received printed tailored educational materials that listed methods that were a "best fit" for them given their responses to the module, as well as methods that were not recommended based on their responses. Methods were categorized on the materials as a best fit (described on materials as "Green: These are the birth control methods that fit your life and goals well and prevent pregnancy best;)" not recommended ("Yellow: These birth control methods are either less good at preventing pregnancy or may be a problem for you;") or medically contraindicated (denoted as "Red"). Project Assistants instructed participants to share the tailored materials with their provider during the visit. Participants in the Intervention + Generic arm used the same module, but received a generic handout that listed the contraceptive methods available at the center. Participants in both groups received, included in their materials, educational information about condoms, abstinence, and emergency contraception; these methods were therefore not ranked by the module. Samples of the tailored and generic handouts are provided in Appendix 1, Figures A3 & A4.

3.B.4 Data Collection

Participant responses to the questions in the computerized assessment module were electronically recorded. Contraceptive method choice was assessed through an interviewer-administered end-of-visit survey at the conclusion of the family planning visit. The wording of the questions and response options for the assessment module and the end-of-visit survey are provided in Appendix 1, Table A1-1 and Table A1-3.

3.B.5 Primary Outcome: Choice of a "Best Fit" Contraceptive Method

The module calculated a ranking score for each contraceptive method based on the individual's responses. As shown in Table 3-1, methods could be ranked by the module as a best fit, not recommended, or medically contraindicated. Participants could also choose a method recommended to all participants or no method. The primary outcome for these analyses is dichotomous: choice of a "best fit" method (yes/no). A more detailed explanation of the operationalization of the primary outcome is provided in Appendix 3, Section 8.A.

Table 3-1. Operationalization of choice of a "best fit" contraceptive method outcome

Module ranking of chosen method	Description of module ranking	Primary outcome
"Best fit" method	A method that is effective and acceptable given participants' responses to the module	Yes
Not recommended	A method that is less effective and/or not suitable for the participants given responses to the module.	No
Medically contraindicated	A method for which there is at least one medical contraindication given responses to module	No
Recommended to all	Methods that are listed on output for all participants in all randomization arms: condoms and abstinence	No
No method	No contraceptive method chosen	No

3.B.6 Data Analyses: Statistical Methods

Data analyses were conducted using STATA 10.1 (StataCorp, College Station, TX). Tabular analyses were conducted, describing the characteristics of the women in the sample.

Additional cross-tabular analyses were conducted, comparing the contraceptive method used at the start of the family planning visit (no method or any method) to the effectiveness of the contraceptive method chosen at the end of the family planning visit (any method [among patients who were using no method at the start of the visit], the same method as was used at the start of the visit, a more effective method than the one used at the start of the visit, an equally effective new method, or a less effective new method). Contraceptive method effectiveness was categorized using WHO effectiveness tiers, as described in Appendix 2, Table A2-4. The number and proportion of sample participants in each cross-tabulated category were calculated.

Finally, the distribution of the primary outcome (choice of a "best fit" method) was compared across subgroup characteristics of participants, using Chi-square tests for categorical variables and ANOVA for continuous variables, with alpha set at 0.05, two-sided, for all significance tests.

3.C RESULTS

3.C.1 Enrollment

In total, 6,502 women were screened for participation in the main trial. Of these, 2,553 (39%) did not meet eligibility criteria, 1,431 (22%) declined participation, and 70 (1%) did not initiate participation after providing consent, yielding 2,448 women who consented and were randomized. Those who were randomized to the control condition (n=547), those in the Intervention arms who did not complete the intervention or the end-of-visit survey on method choice (n=417), and those who completed the intervention and data collection but the algorithm

did not identify a best fit method (n=30) were excluded, leaving a sample size of 1,454 for these analyses. Characteristics of participants excluded from these analyses are discussed in greater detail in Appendix 3, Section 8.B.

3.C.2 Participant Characteristics

As shown in Table 3-2, participants were predominantly foreign-born Latinas. Almost all (99%) participants were either uninsured or enrolled in income-qualifying health programs. No statistically significant (α= 0.05) differences in any of the characteristics listed in Table 3-2 were found between the two intervention groups at baseline (data shown in Appendix 3, Section 8.D.1).

Table 3-2. Sociodemographic characteristics of Intervention + Tailored and Intervention + Generic arm participants (n=1,454)

Characteristic	n	%
Age category		
16-19	216	14.9
20-24	304	20.9
25-29	345	23.7
30-34	306	21.0
35 and older	283	19.5
Race/Ethnicity		
Latina, any race	1025	71.2
Non-Latina black	181	12.6
Non-Latina, non-black	233	16.2
Preferred module language		
English	640	44.0
Spanish	814	56.0
Birthplace		
US	344	23.8
Other countries	1104	76.2
Insurance and income status		
None/self-pay <100% Federal Poverty Level (FPL)	701	49.7
None/self-pay 100-149% FPL	104	7.4
None/self-pay over 150% FPL	27	2.0
Medicaid or other income-eligible public insurance	568	40.3
Private insurance or HMO	11	0.8

Table 3-2, Continued

Educational attainment		
Less than high school	391	27.2
High school graduate/GED	562	39.1
Some college or more	486	33.8
Frequency of computer use		
Never	223	15.4
Infrequent (< once/week)	165	11.4
Once a week or more	1063	73.3

3.C.3 Contraceptive preferences and priorities

Table 3-3 summarizes the contraceptive history, preferences, and sexual and medical history of the women in the sample. More than 45% of the women – none of whom were seeking pregnancy – were using no contraceptive method at the start of their family planning visit, and 38% reported ever experiencing a problem with a birth control method. Side effects (cited by 17% of all participants) were the most common problem; 5% reported their partner did not like a method; and less than 1% reported difficulties in obtaining the method as a problem (problems not mutually exclusive). The majority of patients stated that they did not want to interrupt sexual activity to use contraception (70%) and wanted a method that they could keep private from friends, family or their partner (59%). In response to a question about the three most important factors in a method, the three most frequently cited priorities were: easy to use (cited by 62%), very effective (60%), not many side effects (40%).

The women in the sample are at increased risk of unintended pregnancy: while 98% of participants (who responded to the question) reported that they do not want to become pregnant in the next year (n=1,388), 41% of these women (n=570) were not using any contraception at the start of their family planning visit. Of these 570 women who did not want to be pregnant in the next year and were not using a method of contraception at the start of their visit, 488 (86%) were currently in a sexual relationship, 537 (94%) had had at least one male sex partner in the last year, and 219 (38%) had had at least one unintended pregnancy.

Table 3-3. Contraceptive history, contraceptive preferences, sexual and medical history of Intervention + Tailored and Intervention + Generic participants (n=1,454)

Characteristic	n	%
Contraceptive history		
Ever used contraception	1211	83.5
Contraceptive method used at start of visit [b]		
None	625	45.4
Oral contraceptives (combined or progestin-only)	289	21.0
IUD (Paragard or Mirena)	229	16.6
Condoms	96	7.0
Injectable (Depo-Provera)	90	6.5
NuvaRing	35	2.5
Contraceptive patch	6	0.4
Withdrawal	3	0.2
Breastfeeding	3	0.2
Female barrier methods (diaphragm, sponge, female condom)	2	0.1
Number of unintended pregnancies		
None	853	58.9
One	383	26.5
Two or more	212	14.6
Contraceptive history	**n**	**%**
Not using contraception at first unintended pregnancy (asked of n=595 with any unintended pregnancy)	468	77.9
Ever experienced a problem with a contraceptive method [c]	553	38.4
Contraceptive preferences		
Need to keep method private	834	59.0
Not OK to interrupt sexual activity to use method	993	69.9
Preferred frequency of use of contraception[d]		
Every time you have sex	341	25.1
Every day	330	24.3
Once a week	156	11.5
Once a month	175	12.9
Every three months	194	14.3
Longer than every three months	163	12.0
Permanent method	389	28.6
When want to become pregnant		
Less than one year	31	2.2
1-3 years	183	12.9
3 or more years	355	25.0
Not sure but definitely want to have a baby	400	28.2
Never	450	31.7

Notes: *Missing data not shown*

[b] *Participants who reported using more than one method were categorized according to method of highest typical use effectiveness. Participants who reported concurrent use of more than one hormonal method (n=27) were excluded.*

[c] *Asked only of participants who reported ever using contraception.*

[d] *Responses not mutually exclusive.*

Table 3-3, Continued

Contraceptive priorities	n	%
Most important factors in a method [d]		
Easy to use	854	62.2
Very effective	822	59.9
Not very many side effects	545	39.7
Able to give regular monthly periods	372	27.1
No hormones	288	21.0
Do not need to interrupt sexual activity	269	19.6
Able to get pregnant quickly after stopping method	205	14.9
Inexpensive	184	13.4
Effective long term (three months or longer)	158	11.5
Safe with breast-feeding	155	11.3
Gives fewer periods or no period	111	8.1
Decreases symptoms from period	111	8.1
Sexual history		
Number of male sexual partners in last year, mean (range)	1.4 (0-20)	---
Participant and partner status		
Have sex only with each other	1114	77.8
Have sex with other people	40	2.8
Not sure about partner's sexual activity outside the relationship	168	11.7
Currently not having sex	110	7.7
Medical history		
Any medical condition for which some contraceptive methods may be contraindicated	701	48.2
Menstrual symptoms require missing work or school sometimes or almost every month	292	21.0
Currently taking any medication for which some contraceptive methods may be contraindicated	3	0.2

Notes: *Missing data not shown*
[d] *Responses not mutually exclusive.*

3.C.4 Changes in contraceptive method choice from start of visit to end of visit

Among the 1,378 participants with complete data on method use at the start of their visit, 42% chose a contraceptive method that was different than the one they had been using at the start of their visit, 42% chose the same method as they had been using at the start, and 16% left their visit with no contraceptive method. As shown in Table 3-4, 625 (45%) of the participants were

using no method at the start of their visit. Of these 625 participants, 466 (or 75%) left their visit with any method of contraception.[e]

Table 3-4. Contraceptive method choice at the end of visit among Intervention + Tailored and Intervention + Generic arm participants, by contraceptive method at start of visit, and direction of movement of effectiveness of chosen method from start to end of visit (n=1,378)

Contraceptive method used at start of visit	Contraceptive method choice at end of visit	n	%	Direction of movement of effectiveness of chosen method from start to end of visit
No method	Any method	466	33.8	↑ more effective
Any method	More effective new method	52	3.8	↑ more effective
Any method	Same method	583	42.3	←→ same effectiveness
Any method	Equally effective new method	38	2.8	←→ same effectiveness
No method	No method	159	11.5	←→ same effectiveness
Any method	Less effective new method	22	1.6	↓ less effective
Any method	No method	58	4.2	↓ less effective

Note: *Participants who did not completely answer the question about contraceptive method use at the start of visit (n=49) or who reported concurrent use of more than one hormonal method (n=27) were excluded from this table*

[e] As comparison, among the Control arm participants (who were excluded from these analyses), 48% (241 of 499) of participants in the Control arm were using no contraception at the start of visit (a proportion that did not differ significantly from the 45% in the Intervention arms; Chi-square test p=0.259). Of these 241 Control arm participants, only 159 (66%) left with any method of contraception, a proportion significantly lower than the 75% in the Intervention arms (Chi-square test p=0.011).

3.C.5 Primary Outcome Analysis: Choice of a "Best Fit" Contraceptive Method

Overall, 59% (n=863) of participants chose a method that was a "best fit" for them given their responses to the module. As shown in Table 3-5, women age 16-24 (compared to those 25 and over), non-Latina black women (compared to Latina and non-black women), women who were not using contraception at the start of their visit (compared to those who were), and women with a history of unintended pregnancy (compared to those without) were significantly less likely to choose a method that was ranked by the module as being a "best fit."

Table 3-5. Proportion of Intervention + Tailored and Intervention + Generic arm participants who chose a contraceptive method that was ranked as a "best fit," by sociodemographic characteristics and contraceptive history and preferences (n=1,454)

	Proportion who chose a "best fit" method		
Participant subgroup	**With characteristic n/N (%)**	**Without characteristic n/N (%)**	**Chi-square test of differences p-value**
Intervention arm			
Received tailored health materials (Intervention + Tailored, compared to Intervention + Generic)	477/814 (58.6)	386/640 (60.3)	0.519
Sociodemographic			
Age 16-24 (compared to age 25 and older)	289/520 (55.6)	574/934 (61.5)	**0.030**
Used English module (compared to used Spanish module)	361/640 (56.4)	502/814 (61.7)	**0.047**
Contraceptive history			
Not using contraception at the start of visit	294/625 (47.0)	564/823 (68.5)	**<0.001**
Ever had an unplanned pregnancy	314/595 (52.8)	548/853 (64.2)	**<0.001**
Ever had a problem with a contraceptive method	327/553 (59.1)	528/888 (59.5)	0.902
Contraceptive preferences			
Need to keep method private	506/834 (60.7)	333/580 (57.4)	0.226
Wants to get pregnant 3 or more years from now or never (compared to wanting to be pregnant within the next 3 years, or not sure when)	494/805 (61.4)	388/614 (63.2)	0.482

Individually tailored materials, which listed the methods that were a "best fit," were provided to participants in the Intervention + Tailored arm, but not those in the Intervention + Generic arm. Providing this tailored information, however, did not have an impact

on the distribution of the primary outcome (Chi-square p-value= 0.686). Additional analyses using a categorical outcome of the module ranking of the chosen method confirmed the lack of impact of tailored materials on method choice (data shown in Appendix 3, Section 8.C.1).

The findings revealed stark discrepancies between childbearing intentions and contraceptive choice among the women in the sample. Among the entire sample, 224 (15%) left the family planning visit without any contraceptive method. Of these 224 women, only 3 (1%) reported they wanted to become pregnant in the next year; 57 (25%) reported they wanted to become pregnant 3 or more years from now, 60 (27%) never wanted to become pregnant. More than half of these women (n=123, or 55%) stated that effectiveness was one of the three most important things in a method.

3.D DISCUSSION

No single contraceptive method is ideal for every patient. High-quality contraceptive counseling must integrate information about effectiveness, the patient's preferences and priorities, and medical contraindications [150]; this can be a complex process for the patient and the provider [66, 74]. Previous research has shown that integrating patients' preferences can lead to improved contraceptive use [151, 152, 179]. An understanding of family planning patients' contraceptive histories, preferences and priorities – and how they relate to contraceptive choice – is of public health interest.

In this sample of low-income, predominantly Latina family planning patients, there were mismatches between contraceptive preferences and priorities and contraceptive choice, placing women at increased risk of unintended pregnancy. Fewer than 60% of participants chose an effective method that was a best fit for them, and 15% of participants left their visit with no contraceptive method. Ease of use and effectiveness were the two most commonly cited contraceptive priorities. These contraceptive priorities suggest an opportunity for clinicians to

discuss long-acting reversible contraception with women if such methods fit well with the individual's contraceptive preferences [21, 155, 180].

In the context of an intervention testing a computer-based contraceptive assessment module, family planning patients who had a history of unintended pregnancy and those who were not using contraception at the start of their visit – characteristics that place a woman at increased risk of unintended pregnancy [2, 58, 181, 182] – were less likely to choose an effective contraceptive method that was a best fit with their stated history, preferences and priorities. While computer-based contraceptive assessment module increased the proportion of patients leaving their family planning visit with an effective method [178], providing individually tailored health materials was not found to influence contraceptive method choice: participants who received tailored materials were no more likely to choose a contraceptive method that was a best fit for them, compared to participants who completed the module but received generic materials. These findings echo those of a previous study which found that contraceptive method choice was not consistent with stated contraceptive priorities and was not affected by the level of knowledge about contraceptive method effectiveness [122].

This study has some limitations, as discussed in previous chapters. The intervention was tested in a population of low-income, predominantly non-US-born Latina family planning patients. While there were more than 1 million births to Latina women in the US in 2008 [36], the racial and ethnic composition of the women included in this study does not necessarily reflect that of other groups of family planning patients, and results may not be generalizable to other populations or settings. While individual preferences and priorities were incorporated into the tested intervention, cultural factors were not explicitly examined.

The population studied has allowed analyses to shed light on the role of individual factors in contraceptive decisionmaking. The research that does exist on individual preferences [183, 184] , with some exceptions [122], has not matched up these preferences with

contraceptive method choice. Family planning providers face numerous barriers in providing high-quality contraceptive counseling, including the need for culturally competent counseling, particularly for patients with limited English proficiency; keeping pace with – and conveying – updated information on new contraceptive methods; and the increasing proportion of women of reproductive age who are in need of family planning services [57, 185, 186]. In the absence of an impact of tailored materials on contraceptive method choice – regardless of the impact of tailored materials on contraceptive method continuation, discussed in Chapter 4 – additional research on interventions to increase the proportion of women who choose effective, medically indicated contraceptive methods that fit their priorities and preferences is needed. Potential next steps for such research are discussed in Chapter 5.

4 CHAPTER 4: IMPACT OF CONTRACEPTIVE MODULE AND TAILORED MATERIALS ON METHOD CONTINUATION AT FOLLOW-UP (SPECIFIC AIM 3)

4.A INTRODUCTION

The effectiveness of contraception is influenced not only by the efficacy of the method, but also adherence to the method (the correct, consistent use of the contraceptive method as prescribed or instructed, also referred to as compliance [116-118]), and continuation of the method over time [117, 119, 187]. Discontinuation of contraceptive methods due to side effects [164-166] or barriers in obtaining them [164, 188] is common [189]. It is estimated that more than 1 million unintended pregnancies in the United States each year can be attributed to misuse or discontinuation of oral contraceptives [190]. A review of hormonal contraceptive refill data from 99% of all retail pharmacies over two years (representing nearly 1.7 million women) found that after 90 days, 38.8% to 52.3% of patients had not continued refills of their methods [191]. Adherence is also low [192], and complexities of measuring adherence have resulted in overestimates [116]. A recent study using wireless electronic monitoring to measure adherence with oral contraceptives found that 57% of participants (including those receiving reminder text messages) missed 3 or more pills a cycle [193]. Women of low socioeconomic status have been found to be more likely to experience contraceptive failure or inconsistent contraceptive use, compounding disparities in unintended pregnancies [3, 23, 25, 33, 63, 64]. Two recently-completed randomized controlled trials testing interventions to improve contraceptive continuation – one using a flipchart [129], the other using reminder phone calls [135] – did not increase method continuation at 3 months. A Cochrane review, updated in 2011, revealed that little evidence is available on effective interventions to improve contraceptive method continuation and adherence [81].

Recognizing the lack of proven efficacy among interventions to improve contraceptive choice and continuation [179], a contraceptive assessment algorithm [146] was adapted into a bilingual (Spanish/English) module incorporating audio-computer assisted self-interviewing (ACASI) and touchscreen technology. A randomized controlled trial of the module was conducted in two urban family planning clinics serving low-income predominantly foreign-born Latinas to test the module's efficacy in increasing the proportion of patients choosing effective contraceptive methods and continuing use of the chosen method 4 months later [178].

4.B MATERIALS AND METHODS

4.B.1 Study Design, Aims & Setting

A three-arm randomized controlled trial to test the efficacy of a computer-based contraceptive assessment module in increasing the proportion of patients who continued use of their chosen contraceptive method 4 months after the visit was conducted at two family planning centers in a shared clinical network in New York City.

4.B.2 Participant Recruitment

Over the course of 18 months of recruitment, family planning patients were approached sequentially as they registered for their appointment, and were screened for eligibility. Participant recruitment was conducted by two trained bilingual (Spanish/English) Project Assistants from March 2009 through August 2010, with follow-up conducted through January 2011. English- or Spanish-speaking women age 16 and over, capable of providing informed consent, who presented at the recruitment sites for a family planning visit were eligible for participation in the baseline study. Walk-in pregnancy test patients, women who spoke neither Spanish nor English, and women who were pregnant, seeking pregnancy, who had tubal ligation or a current partner with a vasectomy, or who reported they were going through or completed menopause were not eligible. The study protocol was reviewed and approved by the

Institutional Review Board (IRB) of Public Health Solutions. All eligible participants provided written consent, and received a $10 gift card on the day of their visit. Consent included permission to view clinical and administrative data from the family planning visit and permission to be contacted via telephone 4 months later, if randomly selected for the follow-up study.

4.B.3 Intervention Arms

All participants, once consented, were given a touchscreen laptop computer loaded with an audio-computer assisted self-interviewing (ACASI) module. Participants were randomized to: 1) use the computer-based contraceptive assessment module and receive tailored health materials based on their responses to the module (Intervention + Tailored); 2) use the module and receive generic health materials (Intervention + Generic); or 3) a control condition (Control), as summarized in Table 1-2.

The contraceptive assessment module used by the Intervention + Tailored and Intervention + Generic participants, described in Chapter 2 and Appendix 1, included approximately 50 questions on contraceptive history, preferences, and priorities and medical and sexual health.

Participants in the Intervention + Tailored arm, after interaction with the module, received printed tailored educational materials that listed methods that were a best fit for them given their responses to the module. Methods on the materials were categorized as “Green: These are the birth control methods that fit your life and goals well and prevent pregnancy best;” “Yellow: These birth control methods are either less good at preventing pregnancy or may be a problem for you;” or “Red” for medically contraindicated methods. Project Assistants instructed participants to share the tailored materials with their provider during the visit. Participants in the Intervention + Generic arm used the same module, but received a generic educational handout that listed the contraceptive methods available at the center. Participants in the Control arm answered 10 basic sociodemographic questions using the same ACASI touchscreen interface;

they received the same generic handout as Intervention + Generic participants. Regardless of the arm to which they were randomized, all study participants used the laptops before their visit with a health care provider. Because participants in the Intervention + Tailored group received tailored handouts while those in the Intervention + Generic and Control groups received generic handouts, randomization allocation was not fully blinded to providers.

Block randomization was computerized using a non-deterministic algorithm, determined by the deci-second the participant began the computer survey. Randomization allocation was shifted during the course of recruitment. During the first 11 months of recruitment (starting in March 2009), half of participants were randomized to the Intervention + Tailored arm, and half to the Intervention + Generic arm. After February 2010, 70% of participants were randomized to the Control arm and 30% were randomized to the Intervention + Tailored arm. The changes to the randomization allocation are discussed in greater detail in Chapter 2 and in Appendix 2.

4.B.4 Data Collection: Day of Family Planning Visit

Survey data were collected through self-reported responses to the module. Additional sociodemographic data and provider's report of the contraceptive method chosen at the time of visit were exported from the administrative database. Self-reported contraceptive method choice was assessed through an interviewer-administered survey at the conclusion of the visit (the end-of-visit survey). The wording of the questions and response options for the baseline surveys are provided in Appendix 1, Table A1-1 and Table A1-3.

4.B.5 Random Selection for Follow-Up Survey

A subset of participants was randomly selected on a monthly basis to participate in a telephone survey about contraceptive method continuation 4 months following their visit (Figure 4-1). Using a sampling frame of the sequential ID numbers of participants who completed participation in the baseline study four months prior to the selection month, 15 to 20% of ID

numbers were randomly selected using the random case selection process of SPSS 14.0 (Chicago, IL). Monthly random selection was repeated until a minimum of 100 participants in each randomization arm had been selected. Additional information on the random selection procedures for the follow-up survey is provided in Appendix 4, Section 9.B.1. Participants randomly selected for follow-up did not differ from those not selected on any of the sociodemographic variables tested in Table 4-1, and did not differ on contraceptive method choice. Supporting analyses for these comparisons is provided in Appendix 5, Sections 10.C.1. and Section 10.C.2.

4.B.6 Data Collection: Follow-Up Survey

Telephone interviews were conducted by bilingual (Spanish/English) interviewers who were blinded to the randomization arm status of participants. The wording of the follow-up survey questions and response options is provided in Appendix 4, Section 9.A. Reliability of questionnaire items is discussed in Appendix 4, Section 9.B.

4.B.7 Outcomes

Three contraceptive outcomes at the time of follow-up (4 months after the family planning visit) were compared across randomization arms: use of an effective method of contraception at follow-up; continuation of the contraceptive method chosen on the day of the family planning visit; and adherence to the chosen contraceptive method.

4.B.8 Use of an effective method of contraception 4 months after visit

Effectiveness of the contraceptive method used at follow-up was dichotomized as: effective methods (those with fewer than 10 pregnancies per 100 women in 1 year of typical use [73, 147]); and less effective methods (10 or more pregnancies per 100 women in 1 year of typical use) or no method. Contraceptive methods in the effective group include female sterilization, male sterilization (vasectomy), contraceptive implants (Implanon), and intrauterine devices

(IUDs including Mirena and Paragard), injectable contraceptives (Depo-Provera), combined oral contraceptives, progestin only pills, contraceptive ring (NuvaRing), and contraceptive patch (OrthoEvra). The operationalization of this outcome is explained in greater detail in Appendix 5, Section 10.A.1.

4.B.9 Continuation of chosen method of contraception 4 months after visit

All participants in the follow-up survey were asked whether they were "still using" the contraceptive method they had chosen on the day of their family planning visit; the survey wording included the method of contraception the participant had chosen on the day of their visit. Contraceptive method continuation at 4 months – whether the patient was still using the method chosen at the time of visit – was dichotomized (yes/no). The operationalization of this outcome is explained in greater detail in Appendix 5, Section 10.A.2.

4.B.10Adherence to Contraceptive Method 4 Months after Visit

Each survey participant who reported continued use of their method was asked a question about adherence [116] to the method in the 2 week period before the follow-up survey. The wording of the question on adherence was method-specific: for condom users, "Did you use a condom every time you had sex?;" for oral contraceptive users, "Have you taken your pills in the past 2 weeks?;" for contraceptive patch users, "Did you place a patch in the last 2 weeks?;" and for Depo-Provera users, "Have you had your second shot?". The operationalization of this outcome is explained in greater detail in Appendix 4, Section 1.A.3. The correspondence of the adherence outcome with the continuation outcome is discussed in greater detail in Appendix 5, Section 10.A.3.

4.C DATA ANALYSES: STATISTICAL METHODS

Data analyses were conducted using STATA 10.1 (StataCorp, College Station, TX). Tabular analyses were conducted, comparing characteristics of participants in each arm using ANOVA

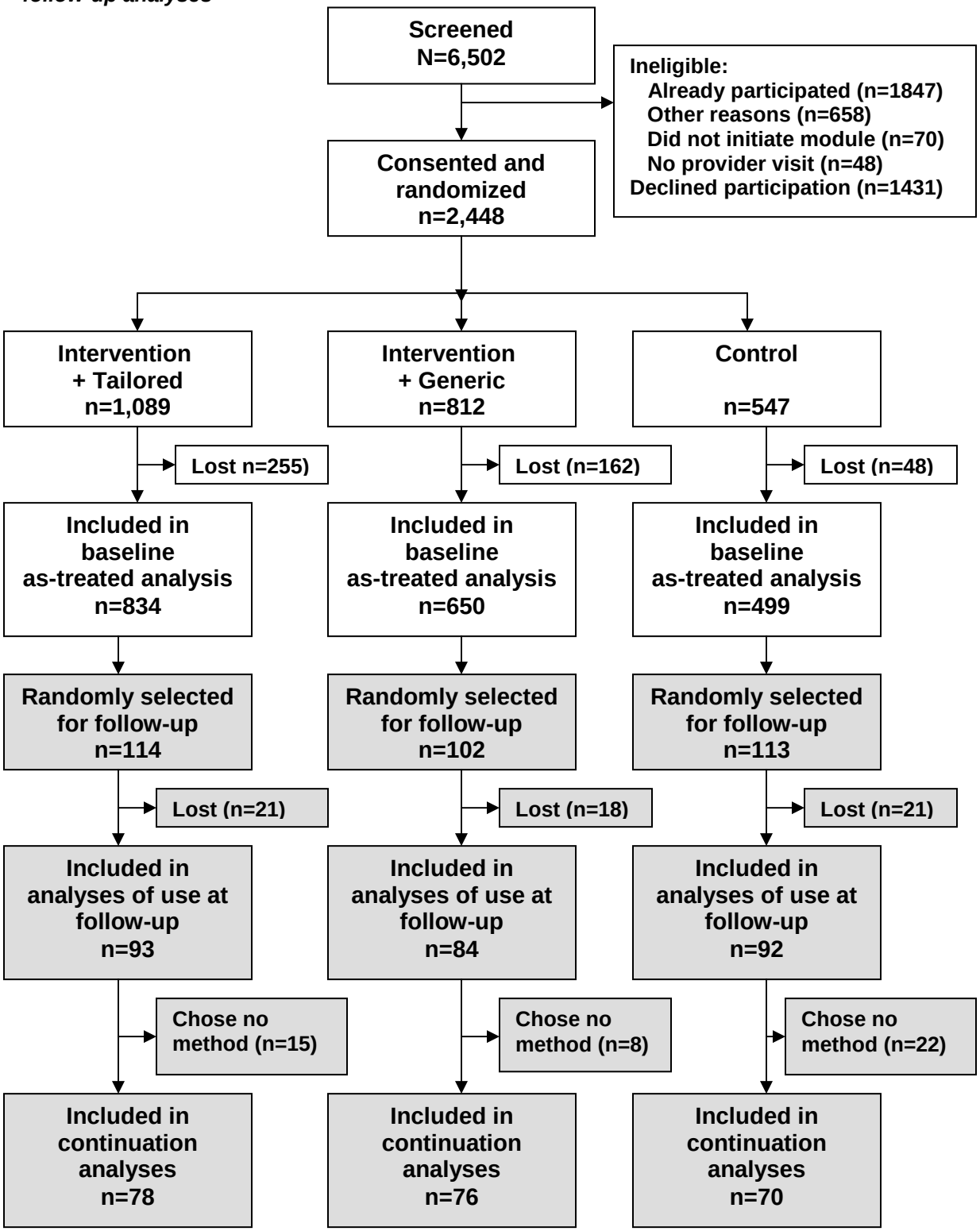
and Chi-square tests, with alpha set at 0.05, two-sided, for all significance tests. The three outcomes – use of an effective method, continuation, and adherence 4 months after visit – were compared across randomization arms, using Chi-square tests and binary logistic regression models controlling for recruitment site, comparing each intervention arm to the control group. Recognizing that odds ratios are an overestimate of risk, relative risk regression models using a log-binomial link were repeated for the continuation and adherence outcomes, comparing each intervention arm to the control group and adjusting for clinical site of recruitment.

4.D RESULTS

4.D.1 Enrollment

As shown in Figure 4-1, a total of 6,502 women were screened for participation in the main trial over the 18 months of recruitment, and 2,448 were eligible, consented to participate, and were randomized. Of those randomized, 1,983 completed the intervention or control condition and data collection on the day of their visit. From these participants, 329 were randomly selected for the 4-month follow-up telephone interview, of whom 269 (81.5%) were successfully contacted and participated in the follow-up interview. The proportion interviewed did not differ significantly across randomization arm (Chi-square p=0.982). Compared to those who participated in the follow-up interview (n=269), those who did not participate (n=60) were younger (mean age 25 compared to 28, ANOVA p=0.006); the groups did not differ significantly on any of the other sociodemographic characteristics assessed (Table 4-1).

Figure 4-1. Flowchart of participant recruitment, randomization, completion and inclusion in follow-up analyses



The sociodemographic characteristics of participants in the follow-up study did not vary significantly across randomization arms; but the center of recruitment did differ, with controls more likely to have been recruited at Site 2 (p=0.003). The 269 participants who completed the follow-up study were predominantly Latina (67%), foreign-born (80%), and low-income (99% had incomes below 200% of the federal poverty line; Table 4-1).

Of the 269 participants who participated in the follow-up survey, 45 (17%) chose no method of contraception on the day of their family planning visit; these patients were excluded from analyses of continuation, resulting in a sample size of 224 for analyses of continuation and adherence. The characteristics of these 224 participants, and the distribution of the characteristics across randomization arms, are presented in Appendix 5, Table A5-8.

Table 4-1. Sociodemographic characteristics of follow-up sample, by randomization arm (n=269)

	Intervention + Tailored (n=93)		**Intervention + Generic (n=84)**		**Control (n=92)**		**Total (n=269)**		**Test of difference across arms (p)**
Characteristic	**Mean (sd)**		**Mean (sd)**		**Mean (sd)**		**Mean (sd)**		**ANOVA**
Age in years, mean (sd)	29.5 (7.3)		28.7 (7.7)		28.6 (7.5)		29.0 (7.5)		0.657
Weight in pounds, mean (sd)	148.4 (30.9)		145.7 (36.6)		139.6 (24.0)		144.6 (30.9)		0.168
Characteristic	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**Chi-square**
Age category									0.914
16-19	8	(8.6)	11	(13.1)	10	(10.9)	29	(10.8)	
20-24	16	(17.2)	15	(17.9)	18	(19.6)	49	(18.2)	
25-29	23	(24.7)	25	(29.8)	24	(26.1)	72	(26.8)	
30-34	22	(23.7)	13	(15.5)	20	(21.7)	55	(20.4)	
35 and older	24	(25.8)	20	(23.8)	20	(21.7)	64	(23.8)	
Race/Ethnicity									0.715
Latina, any race	67	(72.0)	58	(69.0)	56	(60.9)	181	(67.3)	
Non-Latina black	10	(10.8)	11	(13.1)	15	(16.3)	36	(13.4)	
Non-Latina, non-black	15	(16.1)	15	(17.9)	20	(21.7)	50	(18.6)	
Missing or not answered	1	(1.1)	0	--	1	(1.1)	2	(0.7)	
Preferred module language									0.730
English	35	(37.6)	36	(42.9)	39	(42.4)	110	(40.9)	
Spanish	58	(62.4)	48	(57.1)	53	(57.6)	159	(59.1)	
Birthplace									0.988
US	19	(20.4)	17	(20.2)	18	(19.6)	54	(20.1)	
Other countries	74	(79.6)	67	(79.8)	74	(80.4)	215	(79.9)	

Table 4-1, Continued

Characteristic	n	(%)	n	(%)	n	(%)	n	(%)	Chi-square
Insurance and income status									0.07
None/self-pay <100%FPL	53	(59.6)	54	(65.1)	39	(43.3)	146	(55.7)	
None/self-pay 100-149% FPL	5	(5.6)	3	(3.6)	11	(12.2)	19	(7.3)	
None/self-pay over 150% FPL	2	(2.2)	0	---	1	(1.1)	3	(1.1)	
Medicaid or other income-eligible public insurance	29	(32.6)	26	(31.3)	38	(42.2)	93	(35.5)	
Private insurance or HMO	0	---	0	---	1	(1.1)	1	(0.4)	
Clinical site of recruitment									0.003
Site 1	35	(37.6)	26	(31.0)	51	(55.4)	112	(41.6)	
Site 2	58	(62.4)	58	(69.0)	41	(44.6)	157	(58.4)	
Educational attainment									0.568
Less than high school	29	(31.5)	22	(26.2)	21	(23.6)	72	(27.2)	
High school graduate/GED	34	(37.0)	34	(40.5)	43	(48.3)	111	(41.9)	
Some college or more	29	(31.5)	28	(33.3)	25	(28.1)	82	(30.9)	
Frequency of computer use									0.411
Never	19	(20.4)	15	(17.9)	14	(15.2)	48	(17.8)	
Less than once/month	9	(9.7)	3	(3.6)	3	(3.3)	15	(5.6)	
1-3 times/month	2	(2.2)	6	(7.1)	4	(4.3)	12	(4.5)	
Once/week	7	(7.5)	11	(13.1)	9	(9.8)	27	(10.0)	
Several times/week	19	(20.4)	13	(15.5)	21	(22.8)	53	(19.7)	
Every day	37	(39.8)	36	(42.9)	41	(44.6)	114	(42.4)	

4.D.2 Use of any effective method of contraception

Four months after participating in the intervention or control condition, 68% of the 269 participants in the follow-up analysis were using an effective method of contraception (74% in Intervention + Tailored, 69% in Intervention + Generic, and 60% in the Control group, Chi-square p=0.106). After adjustment for the clinical site of recruitment, however, no significant differences were found between the Intervention arms and the Control arm. The regression results, after adjustment, for the Intervention + Tailored group, compared to Control, were not statistically significant (OR=1.74, 95%CI: 0.92-3.28).

4.D.3 Continuation of chosen method of contraception

Of the 224 patients who had chosen a method on the day of their visit, 85% (n=190) reported that they were continuing use of their chosen contraceptive method at the time of follow-up, with module users who received tailored materials significantly more likely to continue their method compared to control group participants (95% compared to 77%, Chi-square test p=0.002; Table 4-2). No statistically significant difference was found between the Intervention + Generic and control group participants (82% compared to 77%, Chi-square test p=0.507).

Table 4-2. Logistic regression and relative risk regression models of continuation of chosen method 4 months after visit, adjusted for clinical site of recruitment (n=224)

	n	Proportion continuing use of chosen method	Odds Ratio (95%CI)	Relative Risk (95%CI)
Intervention + Tailored	78	95%	5.48 (1.72-17.42) p=0.004	1.23 (1.07-1.41) p=0.003
Intervention + Generic	76	82%	1.31 (0.58-2.98) p=0.518	1.06 (0.90-1.25) p=0.504
Control [Ref.]	70	77%	---	---

Note: *Adjusted for clinical site of recruitment. Excludes participants who chose no method at the time of their visit (n=45).*

Of the 34 participants who reported discontinuing their chosen method, 22 (65%) moved to a less effective method or no method, and 6 (18%) to a more effective method, with the remainder moving to a different method in the same effectiveness tier [73]; these changes were not distributed differently across randomization arms (Chi-square p=0.865).

The number needed to treat was calculated using the observed continuation rates in the Intervention + Tailored and Control arms (Table 4-2) [194]. Six patients would need to receive the intervention to prevent one participant from discontinuing their chosen method (NNT=5.64, 95%CI: 3.38-14.19).

4.D.4 Adherence to chosen, continued method of contraception

Of the 224 participants who chose a method of contraception on the day of their visit, 73% of the sample reported adhering to their method. Among the 190 participants who reported continued use of their chosen method (indicating that they were "still using" the method), 14% (n=26) had not used the method in the 2 weeks preceding the interview. Of these 26 patients, 8 (31%) had chosen condoms, 7 (27%) had chosen Depo-Provera, 7 (27%) had chosen oral contraceptives, and 4 (15%) had chosen the contraceptive ring. As shown in Table 4-2, participants who completed the contraceptive assessment module and received tailored health materials, compared to the control arm, were statistically significantly more likely to adhere to use of their chosen contraceptive method (86% versus 69%, Chi-square p=0.011). No significant difference in adherence was found between the Intervention + Generic and control arms (65% versus 69%, Chi-square p=0.600).

Table 4-3. Logistic regression models of adherence to chosen method 4 months after visit, adjusted for clinical site of recruitment (n=224)

	n	Proportion adhering to chosen method	Odds Ratio (95%CI)	Relative Risk (95%CI)
Intervention + Tailored	78	86%	2.74 (1.21-6.21) p=0.016	1.25 (1.04-1.50) p=0.02
Intervention + Generic	76	65%	0.81 (0.40-1.64) p=0.557	0.93 (0.74-1.18) p=0.565
Control [Ref.]	70	69%	---	---

Note: *Adjusted for clinical site of recruitment. Excludes participants who chose no method at the time of their visit (n=45).*

4.E DISCUSSION

In a randomized controlled trial with follow-up 4 months later among a randomly-selected subset of participants, women who used a self-guided computer-based assessment module and received health materials tailored to their responses to the module were significantly more likely

to report continued use of their chosen method and adherence to their chosen method, compared to the control group. The tailored materials, generated from participants' responses to the questions in the module, did not affect contraceptive method choice on the day of the visit in the baseline analyses. Patients in the Intervention + Generic group were equally likely to pick an effective contraceptive method as those in the Intervention + Tailored group on the day of their visit, and they were equally satisfied with the materials (86% found the materials helpful, with no significant difference between those who received generic or tailored materials). Because the contraceptive assessment module identifies methods that are both effective and acceptable given the patient's preferences and contraceptive history, the module could identify two or more methods of equal effectiveness, but of differing acceptability to the individual participant given her responses to the module questions. Participants in the Intervention + Generic arm did not receive tailored information on the relative acceptability of two equally effective methods, and they were no more likely to continue their chosen method or adhere to use, compared to the control group participants.

Despite the findings on continuation and adherence, the module and tailored materials were not found to have an impact on use of any effective method 4 months after the visit, after adjusting for the clinical recruitment site.

The study had some limitations; supplementary analyses were conducted to assess the extent to which they may have affected the findings. The study relied on self-report, which has been found in other studies to result in overestimates of both continuation and adherence [116, 193]. Nevertheless, over-estimation would not be expected to differ across randomization arms; therefore, it would not present an alternative explanation for the observed results. Wording of the adherence question for condom users ("Have you used a condom every time you had sex?") may result in some misclassification of the adherence outcome among condom users at follow-

up (n=26, of whom 8 were classified as not adhering, as shown in Table A5-5) if they had not been sexually active in the last 2 weeks.

This study responds to calls for evidence of the efficacy of interventions to improve contraceptive method continuation [81, 179], particularly for Spanish-speaking Latinas [159]. Because the study was conducted among low-income women seeking family planning services at publicly funded clinics, the findings may not be generalizable to other populations or clinical settings.

Some women who were randomly selected for the follow-up interview were not interviewed, and outcome data on continuation and adherence was not available for those lost to follow-up. Those who were included in the follow-up study differed from those who were not included only in age; no other socioeconomic differences were found. Loss-to-follow-up also did not differ significantly across randomization arms; selection bias is therefore not a likely source of bias. Additional analyses examining potential selection bias as a result of loss-to-follow-up are presented in Appendix 5, Section 10.C.2.

Length of use of the chosen contraceptive method was examined as a potential confounder in the observed results; as shown in Appendix 5, Section 10.C.4., the proportion of patients who chose a new method (as opposed to a method they had already used) did not differ across randomization arms.

A full 95% of the Intervention + Tailored arm participants continued use of their chosen method, compared to 77% of those in the Control arm. Despite this sizable absolute difference, the small sample size of the follow-up analyses limits the ability to draw robust conclusions about the impact of the intervention on continuation and adherence. Because of the small sample size, the movement of a small number of subjects from one method choice outcome category to another between the two survey dates markedly influenced the statistical significance. Of the 45 subjects who had not chosen a method of contraception on the day of

their visit (and who were excluded from the analyses of continuation and adherence), 7 were using an effective method at the time of follow-up: 5 in the Control arm (3 moved to IUD, and 2 moved to oral contraceptives), and 2 in the Intervention + Tailored arm (2 moved to IUD). Additional analyses examining small sample size are presented in Appendix 5, Section 10.D.

The findings are in agreement with previous research indicating that patient-centered counseling can influence contraceptive method choice and use [33, 74-78, 179], and with a trial of a structured contraceptive counseling tool by Langston et al. whose findings were suggestive of a positive impact on continuation [129]. Consistent with findings in the context of other health behaviors, notably condom use, tailored health messages were found to be more effective than generic health messages in changing behavior [143, 195]. As discussed in Chapter 5, additional evaluation of the impact of the intervention on continuation and adherence in a sample large enough to enable robust analyses over a longer time period would be warranted.

5 CHAPTER 5: SUMMARY & RECOMMENDATIONS

5.A SUMMARY OF FINDINGS

The dissertation research was developed to address gaps in the evidence: few single-session interventions had been found to have a significant impact on contraceptive method choice or continuation; few interventions were designed for use by low-literacy, low educational attainment or Spanish-speaking populations; and few studies were of high quality in terms of study design or sample size. Significant findings for two of the three Specific Aims are responsive to calls in the field for high-quality evidence on interventions to improve contraceptive choice and use (Chapter 1).

5.A.1 Specific Aim 1: Impact of the Module on Contraceptive Method Choice

In a randomized controlled trial among 2,448 family planning patients at two federally-funded clinics, family planning patients who used a self-administered computer-based contraceptive assessment module were significantly more likely to choose an effective method of contraception on the day of their visit (a method with fewer than 10 pregnancies among 100 women in a year of typical use), compared to patients assigned to a control condition: 75% of patients in the Intervention + Tailored arm and 78% in the Intervention + Generic arm chose an effective method of contraception, compared to only 65% in the Control arm (OR=1.56 [95% CI: 1.23-1.98] for Intervention + Tailored; OR=1.74 [95% CI: 1.35-2.25] for Intervention + Generic; adjusted for clinical site of recruitment). Analyses testing hypotheses for Specific Aim 1 included intent-to-treat analyses using clinical-administrative outcome data (n=2,231) and as-treated analyses (among n=1,983 patients who completed the intervention or control condition and data collection procedures on the day of the visit) using clinical-administrative and patient self-report outcome data. These findings held in sensitivity analyses subjecting the intent-to-

treat analyses to conservative assumptions about the distribution of missing data. The module was also found to have a positive effect on contraceptive method choice specifically among patients who were using no contraception at the start of their visit. No statistical interaction was observed between the intervention and selected sociodemographic characteristics (age or language of module) or clinical site of recruitment, but a test of statistical interaction with the contraceptive use status at the start of the visit was of borderline statistical significance.

5.A.2 Specific Aim 2: Impact of Tailored Health Materials on Contraceptive Method Choice

In analyses among family planning patients who completed the intervention (n=1,454), participants who used the module and received individually tailored health materials (Intervention + Tailored) were no more likely that those who used the module but did not receive individually tailored materials (Intervention + Generic) to choose a contraceptive method that was identified as a "best fit" by the module (that is, both effective and acceptable given the individual's responses). Overall, 59% of participants chose a method that was a "best fit" for them given their responses. These findings echoed those from as-treated analyses in Specific Aim 1 (among n=1,983), which found no impact of tailored health materials on choice of an effective method of contraception.

5.A.3 Specific Aim 3: Impact of Module on Contraceptive Use and Continuation 4 Months after Family Planning Visit

While analyses for Specific Aims 1 and 2 did not find an impact of tailored health materials on choice of contraceptive method compared to generic materials, analyses of contraceptive method continuation and adherence 4 months after the day of the family planning visit found a significant impact of tailored health materials. In follow-up analyses among a randomly-selected subset of participants from the as-treated sample who had chosen a method of contraception on the day of their visit (n=224), participants in the Intervention + Tailored arm were significantly

more likely to continue (95%) and to adhere to (86%) their chosen method, compared to those in the Control arm (77% and 69, respectively) (Continuation OR= 5.48 [95%CI: 1.72-17.42]; Adherence OR=2.74 [95%CI: 1.21-6.21], adjusted for clinical site of recruitment). No significant difference in continuation or adherence was observed between the Intervention + Generic arm and the Control arm.

Analyses of use of any effective contraceptive method 4 months after the family planning visit did not reveal significant differences across the randomization arms. These analyses, however, were hampered by the small sample size, further exacerbated by the need to control for the imbalance of randomization across clinical site, which limited statistical power.

5.A.4 Descriptive Analyses

The descriptive analyses not testing Specific Aim hypotheses (presented in Chapter 3 and in Appendices 2 and 4) provide a detailed look at the contraceptive history, preferences and priorities of almost 1,500 women seeking family planning care through two federally funded clinics. The participants – predominantly low-income, foreign-born young Latina women – were at elevated risk of unintended pregnancy: while almost 98% of the intervention participants (n=1,454) reported that they did not want to get pregnant in the next year, 15% left their visit without a contraceptive method; this compares to 23% of those in the control condition (n=499 in as-treated analyses).

5.B METHODOLOGICAL CONSIDERATIONS

5.B.1 Internal Validity

The research was designed to maximize internal validity by using a randomized controlled trial study design itself, and through data collection to enable analyses to assess threats to validity.

5.B.1.a Confounding

By design, a randomized controlled trial should remove all measured and unmeasured confounding. As discussed in Chapters 2 and 4, randomization allocation was changed 11 months after participant recruitment began, introducing the possibility of confounding by clinical site and by time. Because of the shift in the randomization allocation, a larger proportion of control patients were recruited at the clinical site at which effective contraceptive methods were less prevalent, introducing confounding by site (discussed further in Appendix 2), requiring statistical adjustment in analyses for the clinical site of recruitment. Findings on choice of an effective method of contraception (Specific Aim 1) and continuation of chosen contraceptive method 4 months after visit (Specific Aim 3) were significant even after adjustment for clinical site.

Confounding by time was also considered, but additional analyses of changes in contraceptive prescribing patterns in the network as a whole suggested that such confounding would bias toward the null.

5.B.1.b Selection Bias

Intent-to-treat analyses among all family planning patients who were randomized (n=2,448) differed little from the as-treated analyses (n=1,983), indicating that non-completion, which was more common among module users than among control participants, was not a source of selection bias.

5.B.1.c Information Bias

Collection of outcome data from both the patient self-report and the clinical-administrative database enabled multiple analyses that indicated information bias was not a threat to internal validity. As-treated analyses using patient self-report of contraceptive method choice differed slightly from the as-treated analyses using clinical-administrative data, but conclusions about

the positive impact of the module on contraceptive method choice remained the same, suggesting that differences in reported contraceptive method choice between the two sources was not a source of information bias.

Sensitivity analyses of these intent-to-treat findings, under conservative assumptions about the distribution of the outcome for those missing outcome data in the clinical-administrative database (n=190), also indicated that information bias due to missing data was not a threat to internal validity.

5.B.2 Statistical power

The study as a whole was amply powered to detect significant differences across randomization arms for analyses of contraceptive method choice on the day of the family planning visit (Specific Aims 1 and 2); the necessity of adjusted analyses to account for imbalance of the randomization arms across recruitment sites, however, hampered statistical power.

For analyses on use and continuation 4 months after the visit (testing hypotheses of Specific Aim 3), starting with a sample size of only 269 follow-up survey participants, and after adjustment for clinical site, a lack of significant findings of the impact of the intervention on use of any effective method of contraception may be attributed to insufficient statistical power.

5.B.3 External validity

The patients included in the study are low-income, predominantly foreign-born Latina family planning patients. The study population was specifically chosen to test a bilingual intervention that was designed to be accessible to women of all literacy levels.

The inclusion and exclusion criteria for the study must be considered when extrapolating the impact of findings to the broader family planning patient population. For example, the study excluded those with partners relying on vasectomy; this underestimates slightly the proportion of women at risk of unintended pregnancy. Conversely, the study did not exclude women who

may not currently be sexually active; therefore, women at low risk of unintended pregnancy were included. Patients who were designated as family planning patients but who were seeking care for reproductive health services other than contraception (e.g. cervical cancer screening or sexually transmitted infection treatment) could not be excluded. The unintended pregnancy risk profile of women included in the study, therefore, does not necessarily represent, in total, that of family planning patients at other centers. The variation in the impact of the intervention on contraceptive method choice between women who were and were not using contraception at the start of their visit (Appendix 2), while not achieving significance for statistical interaction, suggests that the findings may not be generalizable to family planning providers serving patient populations with different contraceptive method mix profiles.

5.B.4 Theoretical Basis

A systematic review of theory-based interventions to improve contraceptive method use, summarized in Chapter 1, suggested that interventions that are theory-based may be more effective than interventions that partially implement a theory or model. While the majority of the theory-based interventions (10 of 14) included in the systematic review had at least one positive impact, no single underlying theory resulted in significant impact across studies [82, 83].

The intervention tested incorporates principles of motivational interviewing, in that it is both client-centered and goal-directed [196, 197]. Because the underlying algorithm assigns higher scoring to more effective contraceptive methods, the intervention is directive. The module asks questions about the participant's preferences and priorities, and asks about barriers to behavior change (for example, problems and barriers in past contraceptive use) [78]. Questions regarding pregnancy intention coupled with questions about past and current contraceptive use identify discrepancies between behaviors and broader goals (referred to as "ambivalence"). Despite incorporating these features of motivational interviewing, the intervention is not explicitly theory-based, and the intervention does not include essential features of motivational

interviewing such as open-ended questions. The findings from the analyses therefore cannot support or refute the motivational interviewing theoretical framework.

5.B.5 Features of the Intervention

5.B.5.a Ensuring standardized, high-quality contraceptive assessment and counseling

A 2009 Institute of Medicine report on the impact of federally-funded family planning programs cited education and counseling as a core service that must be offered to every client, yet acknowledged that meeting the counseling requirements limits the number of clients that can be served [185]. The Bruce-Jain framework, published in 1990, has served as a basic paradigm for defining quality of care [198]. More recently, a framework developed collaboratively by the Population Council and the Population Reference Bureau identified 13 key quality of reproductive health care indicators, including demonstrating "good counseling skills (p. 6)," asking client about reproductive intentions (desired number, timing, and spacing of children), asking client about preferred method, tailoring information to the client's needs, and recognizing medical contraindications [150]. The intervention tested specifically integrates 5 of these quality indicators. The self-guided computer-based module provides standardization of contraceptive assessment, limiting potential provider bias or preference [34, 173]. At the same time, the interactive nature of the intervention allows tailoring of contraceptive advice to patients' needs.

5.B.5.b Addressing needs of women with low educational attainment and limited English proficiency

Research has shown that functional health literacy – the ability to obtain, process, and understand health information – affects health care quality, use, outcomes, and disparities [137, 138, 156]. There are an estimated 47 million adult women in the United States with limited literacy skills [145]. The format of the intervention was developed to be accessible to women of all literacy levels. The computer-based intervention, which used touch-screen and audio-computer assisted self interviewing (ACASI) technology so that no reading or typing is required,

addresses the needs of women with low educational attainment, who are at risk of unintended pregnancy [139, 157, 158].

The intervention also responds to the health information needs of Spanish-speaking women with limited English proficiency. As the Latina population of reproductive age continues to grow nationally [199] there is great need for research and interventions relating to contraceptive use for this population subgroup [159].

5.B.5.c Potential for replication

The intervention was low-intensity; there is little prior evidence in the literature of single-session interventions that have been found to be effective in changing contraceptive choice or use (Chapter 1). The intervention tested did not require provider training before implementation. The technical requirements were a touchscreen laptop computer and printer. As such, the intervention can easily be replicated in other sites and settings.

5.C RECOMMENDATIONS FOR FUTURE WORK

While the dissertation research has numerous strengths, and there are few barriers to implementing the intervention more widely, additional research and evaluation of the intervention is merited to address some limitations and unanswered questions in the findings.

5.C.1 Effectiveness research

Further research is needed on the effectiveness (rather than efficacy) of the intervention – that is, the effect of the intervention under "real-world" conditions of implementation, in a broadly defined population [200-202]. While there was not evidence of statistical interaction between contraceptive use status at the start of the visit and the intervention, the effect of the intervention on contraceptive method choice did vary between women who were and were not using contraception at the start of their family planning visit. Further evaluation of the impact of the intervention is warranted at a range of clinical sites or settings and with other patient

populations. The RE-AIM evaluation framework, which incorporates the phases Reach (the proportion participating and characteristics of those who participate), Effectiveness (impact on outcomes), Adoption (representativeness of settings), Implementation (intervention fidelity, consistency and quality) and Maintenance (sustained impact over time), can serve as a model for further effectiveness research [203, 204].

5.C.2 Assessing impact on provision of care

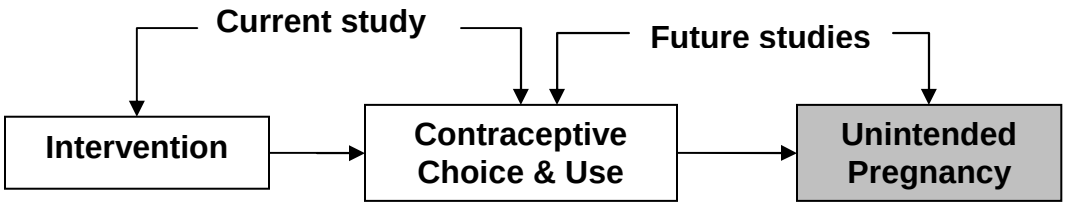
The intervention may be easily replicable, but the potential impact of integration of the module on clinical care cannot be assessed using the existing dataset because the study was not designed to answer these questions. The intervention was conducted at the patient level, without training of providers or data collection on impact of the module on the provision of care from the provider's perspective. Clinical indicators, such as visit time, wait time, provider perception of the impact of the intervention, were not collected. Most notably, data were not collected on whether the participant shared the tailored materials with the provider; data on whether participants had shared the tailored materials with the provider could have shed additional light on the interpretation of a lack of significant impact of tailored materials on choice of a "best fit" contraceptive method (Chapter 3).

As discussed in Chapter 1, few interventions have found significant positive impact on contraceptive choice and use. Interventions that were found to positively impact contraceptive outcomes resulted in longer visit times with the provider [69, 205]. Further examination of the impact of the intervention, either benefits or drawbacks, from the perspective of both the patient and the provider, would add to the efficacy shown in this study.

5.C.3 Long-term outcomes

Reducing unintended pregnancy is the long-term goal of interventions to improve contraceptive choice and use.

Figure 5-1. Objective and long-term goal of contraceptive interventions



The objective of the present study was to examine the impact of the intervention on contraceptive choice and use (Figure 5-1). Research on the impact of interventions on unintended pregnancy is methodologically difficult [43, 79], particularly given the difficulties in measuring pregnancy intention [19, 27, 28, 41, 45] . Nevertheless, research of surrogate outcomes – such as pregnancy rates [92] and pregnancy spacing – is an ideal next step toward the long-term goal.

At a minimum, given the limited statistical power for analyses of Specific Aim 3 (Chapter 4), the effectiveness research discussed above should examine the impact of the intervention on contraceptive use, continuation, and adherence in a larger study sample and over a longer period of time.

5.C.4 Cost-Effectiveness

Research has shown that increasing the use of highly effective contraceptive methods can reduce health care costs by averting unintended pregnancies and induced abortions [22, 206]. Analyses estimate that for each dollar spent on family planning care, four dollars are saved [7, 181, 206]; in fact, analyses suggest that using any contraceptive method is a cost-effective

strategy [206]. The potential impact of wider use of the intervention, in terms of cost savings attributed to changes in the distribution of contraceptive method choice as a result of the intervention [207], merits investigation.

5.D PUBLIC HEALTH SIGNIFICANCE

The proportion of pregnancies that are unintended – nearly half of all pregnancies – has not decreased in the last decade [3]. The overall pregnancy rate has increased in the last 5 years, resulting in an increasing number of unintended pregnancies: from 2001 to 2006, the number of unintended pregnancies occurring in the United States increased from an estimated 3.1 million to 3.24 million [2, 3].

Recognizing the prevalence, persistence, disparities and costs of unintended pregnancy, Healthy People 2020 includes a goal of increasing the proportion of pregnancies that are intended through the use of contraception [60]. Half of unintended pregnancies could be averted if more effective contraceptive methods were used [160]. The intervention tested in this dissertation has the potential to contribute to these long-term public health goals. Effectiveness research on the real-world implementation of the intervention can contribute to some of the gaps of the present research.

Beyond such research, replication of an intervention to improve the choice and continued use of effective and acceptable contraceptive methods within the network of family planning centers funded through the federal Title X family planning program has the potential to improve reproductive health outcomes for millions of medically underserved women at high risk of unintended pregnancy. Family planning centers receiving Title X funds serve as a gateway to health care for millions of women: 60% of women receiving care at Title X-funded centers reported that the family planning center is their usual source of medical care [208]. In 2008 alone, the Title X federal family planning program served more than 5 million women through 4,500 provider sites [185].

6 APPENDIX 1: DATA COLLECTION FOR CHAPTERS 2 & 3

6.A DATA COLLECTION & SOURCES OF DATA

6.A.1 Self-Report Data: ACASI Module

Self-report data were collected through the module; skip patterns and variable coding were programmed into the module. Participants completed interaction with the touchscreen laptop (either the module or the control condition) before their visit with a health care provider. Participants in the control group were only asked 10 demographic questions using the same ACASI interface as those in the intervention arms; these 10 questions are indicated in Table A1-1 with an asterisk (*). In accordance with IRB requirements, all participants had the option of responding “I don’t know” or “I prefer not to answer” to each question.

Table A1-1. Module Questionnaire: Variables, question wording, and response options

Variable Name	Question	Response Options
Q1	How old are you?*	[Enter on keypad]
Q2	How tall are you?*	[Slide on scale]
Q3	How much do you weigh?*	[Enter on keypad]
Q4	What is your race or ethnicity? You may select as many as you would like.*	
Latino		Latino, Hispanic or Chicano
Black		Black or African American
White		White
Asian		Asian
Hawaiian		Native Hawaiian or Other Pacific Islander
AmIndian		American Indian or Alaska Native
Other		Other
Q5	Were you born in the United States or in another country?*	
US		United States
othercountry		Another country

Table A1-1, Continued

Variable Name	Question	Response Options
Q6	What is the highest level of education you have completed?*	
Lessthan		Less than high school
GED		High school graduate or GED
Nodegree		Some college but no degree
Associate		2-year college degree or Associate's Degree
BA		4-year college degree, BA or BS
graduate		Graduate or professional school
Q7	How often do you smoke cigarettes or cigars or use smokeless tobacco?*	
Nosmoke		I do not use tobacco
lessmoke		I use tobacco less than once a day
dailysmoke		I use tobacco daily
Q8_intro	Now I'm going to ask you some questions about your period.	
Q8	When you are not using birth control, do you have regular monthly periods?	Yes/No
Q8.a	Do you have three or fewer periods per year?	Yes/No
Q9	When you are not using birth control, do you have very heavy periods?	Yes/No
Q10	When you are not using birth control, do you have periods that last longer than 7 days?	Yes/No
Q11	When you are not using birth control, do you have painful periods or bad cramps?	Yes/No
Q12	When you are not using birth control, do you have breast tenderness during your period?	Yes/No
Q13	When you are not using birth control, do you have depression or anxiety during your period?	Yes/No
Q14	When you are not using birth control, do you have bloating or fluid retention during your period?	Yes/No
Q15	When you are not using birth control, do you have bad headaches with your period?	Yes/No
Q16	When you are not using birth control, do you have significant PMS (premenstrual syndrome)?	Yes/No
Q17	How often do these symptoms cause you to miss work or school?	
		Rarely/Never
		Sometimes
		Almost every month

Table A1-1, Continued

Variable Name	Question	Response Options
Q18	How would you describe your current sexual relationship? Would you say that…	
Monogamous		your partner and you have sex only with each other
Multiplepartner		your partner *or* you have sex with other people as well
Notsure		you are not sure about your partner's sexual activity outside your relationship
nosex		you currently are not having sex?
Q19	During the last 12 months how many men, if any, have you had sexual intercourse with? Please count every male sexual partner, even those you had sex with only once.	[Number pad]
Q20	Have you ever had an unplanned pregnancy?	Yes/No
Q20.a	How many unplanned pregnancies have you had?	[Number pad]
Q20.b	The [x] time you had an unplanned pregnancy, were you using any method of birth control or doing anything to prevent getting pregnant?	Yes/No
Q20.b.i	The [x] time you had an unplanned pregnancy, what method of birth control were you using?	
Pill		The pill or birth control pills (containing both an estrogen and progestin)
Minipill		"Mini-pills" or progestin-only pills
Patch		Ortho Evra contraceptive patches
Ring		NuvaRing, the vaginal contraceptive ring
Depo		Depo Provera, the birth control shot
EC		Emergency contraceptive pills (also called the morning after pill or Plan B)
Condom		Male condom
Cap		Diaphragm or Cervical cap
Reality		Reality female condom
sponge		Today contraceptive sponge
Copperiud		Paragard Copper T IUD (Intrauterine Device)
Mirena		Mirena Hormonal IUD (Intrauterine Device)

Table A1-1, Continued

Variable Name	Question	Response Options
tubestied		Permanent sterilization for women, also called tubal ligation or getting your tubes tied
vasectomy		Permanent sterilization for men, or vasectomy
Implant		Contraceptive implant, sometimes called Norplant or Implanon
Abstinence		Abstinence
Withdrawl		Pulling out or withdrawal
Foam		Vaginal spermicides like foam, film, gel or suppositories
diaphragm		Diaphragm
breastfeeding		Breastfeeding as a birth control method
Q21-A	What birth control methods are you interested in using now?	[Repeat options from Q20.b.i]
Q22	Have you EVER used any method of birth control? *	Yes/No
Q22.a	Are you using birth control now?*	Yes/No
Q22.a.i	What birth control methods are you using now?	[Repeat options from Q20.b.i]
Q23	Have you ever used a birth control method that you didn't like, that didn't work for you, or that you had other problems with?	Yes/No
Q23.a	Which methods did you have a problem with?	[Repeat options from Q20.b.i]
Q23.a.i	What problems did you have while using _____?	
Bodychanges		Didn't like the changes to your body
getting		Problems getting the birth control
use		Didn't use it right
Pregnant		Got pregnant
Health		Developed health problems
Periods		Didn't like your periods
partner		Your partner didn't like it
None		None of these problems
Whatbodychanges		*What were the changes to your body? Please choose all that apply.*
Breast		Breast tenderness
Cramping		Cramping or pain
Hair		Hair loss

Table A1-1, Continued

Variable Name	Question	Response Options
Depression		Depression or mood swings that clearly became worse on the method
Nausea		Nausea or vomiting
Weight		Weight gain
Migraines		Migraines or very bad headaches
Discharge		Discharge
Otherbodychanges		Other changes to your body
Whatgetting		*What were the problems getting the birth control? Please choose all that apply.*
Noclinic		Couldn't get to the clinic or doctor's office to get it
Nopharmacy		Couldn't get to the pharmacy to pick up the prescription
Expensive		It was too expensive
Othergetting		Other problem getting the birth control
Whatuse		*What problems did you have using it correctly? Please choose all that apply.*
Forgot		Forgot to take it or missed too many doses
Restart		Failed to restart after break for period
Everytime		Didn't use it every time you had sex
Otheruse		Another problem using it correctly
whathealth		*What were the health problems that developed? Please choose all that apply.*
HTN		High blood pressure
Bloodclot		Blood clot in vein or lungs
Stroke		Stroke or heart attack
Otherhealth		Another health problem
Whatperiods		*What didn't you like about your periods? Please choose all that apply.*
Prolonged		Didn't like the prolonged bleeding
Heavy		Didn't like the heavy bleeding

Table A1-1, Continued

Variable Name	Question	Response Options
Irregular		Didn't like the irregular bleeding
Nobleed		Didn't like the absence of bleeding
Otherperiod		Didn't like something else about your periods
Q24	How soon do you want to get pregnant? In…*	
Q24lessthan		Less than one year
1to3		In one to three years
3plus		In three or more years
Q24notsure		Not sure when but definitely want to have a baby
never		Never
Q25	What is most important to you when choosing a birth control method? Please select the **three most important** to you.	
Q25_prompt_2		
Q25_prompt_1		
Easy		Easy to use
Safe		Safe with breast-feeding
Cheap		Inexpensive
Effective		Very effective
Q25pregnant		Able to get pregnant quickly after stopping use of method
Nosides		Not very many side-effects
Hormones		No hormones
Longterm		Effective long term meaning three months or longer
Interrupt		Do not need to interrupt sexual activity
Regular		Able to give regular monthly periods
Fewer		Gives fewer or no period
Lowsymptoms		Decreases symptoms from period

Table A1-1, Continued

Variable Name	Question	Response Options
Q26	How often do you want to actively do something for your birth control? You may choose more than one answer.	
Q26Everytime		Every time you have sex
Everyday		Every day
Weekly		Once a week
Monthly		Once a month
3months		Every three months
More3months		Longer than every three months
Permanent		Permanent method
Q27	Would you be okay with regular, scheduled bleeding?	Yes/No
Q28	Would you be okay with unscheduled bleeding and/or spotting?	Yes/No
Q29	Would you be okay with no bleeding at all?	Yes/No
Q30	Do you need a birth control method which you can keep private?	Yes/No
Q30.a	Do you want to keep it private from your boyfriend/girlfriend/partner?	Yes/No
Q30.b	Do you want to keep it private from your family or your friends?	Yes/No
Q31	Would it be OK for you to use a birth control method (like condoms, spermicides, diaphragm or sponge) that you have to interrupt sexual activity to use?	Yes/No
Q32_intro	Because you cannot use some birth control methods if you have certain medical conditions, I am going to ask you some questions about your medical history.	Yes/No
Q32	Have you had a baby in the last 6 months?	Yes/No
Q32.a	Was your baby born less than 3 weeks ago?	Yes/No
Q32.b	Are you breastfeeding a child now?	Yes/No
Q33	Has a doctor, nurse, or other health professional EVER told you that you had high blood pressure, also called hypertension?	Yes/No
Q33.a	Are you taking medicine for high blood pressure now?	Yes/No
HPNpregnancy		Yes, I had high blood pressure during a pregnancy, but not now
HPNbefore		Yes, I was once told I had high blood pressure, but now I don't know
HPNnow		Yes, I have high blood pressure now

Table A1-1, Continued

Variable Name	Question	Response Options
Q34	Has a doctor, nurse, or other health professional EVER told you that you had blood clots, also called clot in a vein or DVT?	Yes/No
Q35	Has a doctor, nurse, or other health professional EVER told you that you had pulmonary embolus, also called a clot in the lung?	Yes/No
Q36	Have you had surgery in the past three months?	Yes/No
Q36.a	Is it hard moving around because of the surgery?	Yes/No
Q37	Has a doctor, nurse, or other health professional EVER told you that you had diabetes?	Yes/No
Q37.a	Have you had diabetes for more than 20 years?	Yes/No
Q37.b	Do you have problems with your kidneys, eyes or nerves because of diabetes?	Yes/No
Q38	Has a doctor, nurse, or other health professional EVER told you that you had a stroke?	Yes/No
Q39	Has a doctor, nurse, or other health professional EVER told you that you had a clotting disorder?	Yes/No
Q40	Do you have migraine headaches?	Yes/No
Q40.a	Do you have migraine headaches with an aura? An aura is seeing spots or wavy lines before or during the migraine headache.	Yes/No
Q41	Has a doctor, nurse, or other health professional EVER told you that you had a molar pregnancy?	Yes/No
Q42	Has a doctor, nurse, or other health professional EVER told you that you had AIDS?	Yes/No
Q43	Has a doctor, nurse, or other health professional EVER told you that you had pelvic tuberculosis?	Yes/No
Q44	Has a doctor, nurse, or other health professional EVER told you that you had toxic shock syndrome (TSS)?	Yes/No
Q45	Has a doctor, nurse, or other health professional EVER told you that you had high cholesterol?	Yes/No
Q46	In the past 3 months has a doctor, nurse, or other health professional told you that you had pelvic inflammatory disease (PID)?	Yes/No
Q47	Has a doctor, nurse, or other health professional EVER told you that you had endometriosis?	Yes/No
Q48	Has a doctor, nurse, or other health professional EVER told you that you had cancer or a malignancy of any kind?	Yes/No
48.a	Have you ever had breast cancer, liver tumors or liver cancer?	Yes/No
48.b	Have you ever had endometrial cancer, ovarian cancer, or cervical cancer?	Yes/No
Q49	Has a doctor, nurse, or other health professional EVER told you that you had a heart attack, also called a myocardial infarction, heart disease or vascular disease?	Yes/No
Q50	Has a doctor, nurse, or other health professional EVER told you that you had complicated valvular heart disease?	Yes/No

Table A1-1, Continued

Variable Name	Question	Response Options
Q51	Has a doctor, nurse, or other health professional EVER told you that you had liver or gallbladder problems?	Yes/No
Q51.a	Has a doctor, nurse, or other health professional EVER told you that you had gallbladder disease or gallstones?	Yes/No
Q51.b	Has a doctor, nurse, or other health professional EVER told you that you had cirrhosis or active hepatitis?	Yes/No
Q52	Has a doctor, nurse, or other health professional EVER told you that you had a seizure disorder or epilepsy?	Yes/No
Q53	Has a doctor, nurse, or other health professional EVER told you that you had sickle cell anemia?	Yes/No
Q54	Has a doctor, nurse, or other health professional EVER told you that you had anemia, sometimes called low blood or tired blood?	Yes/No
Q55	Do you have severe acne?	Yes/No
Q56	Do you have coarse, dark hairs on your face?	Yes/No
Q57	Do you take dietary supplements or prescription medications regularly?	Yes/No
Q57.a	Do you take St. John's wort?	Yes/No
Q57.b	Do you take Rifampin, Rifadin or Rimactane?	Yes/No
Q57.c	Do you take any of these medications for seizure disorders or epilepsy? • Phenytoin or Dilantin • Carbamazepine or Tegretol • Primadone or Mysoline • Topiramate or Topamax • Oxycarbazepine or Trileptal	Yes/No
Q57.h	Do you take Griseofulvin, Fulvicin or Grisactin?	Yes/No
Q58.a	The birth control pill requires that you take a pill every single day. Could you remember to take a pill every single day?	Yes/No
Q58.b	The birth control shot requires that you to return to the clinic every three months to get a shot, would you be able to do this?	Yes/No
Q58.c	The contraceptive patch requires that you wear a patch similar to a band aid that needs to be changed once per week, would you feel comfortable wearing a small sticky patch for birth control?	Yes/No
Q58.d	The contraceptive ring requires that you place a small bendable ring in your vagina once per month. Would you feel comfortable using the ring as a birth control method?	Yes/No

Table A1-1, Continued

Variable Name	Question	Response Options
Q58.e	Would you feel comfortable having an IUD, a T-shaped contraceptive, placed by your provider inside your uterus that would provide contraception for 5-10 years?	Yes/No
Q58.f	The contraceptive implant is a small rod placed by your provider under the skin of your upper arm that provides contraception for up to 3 years. Would you feel comfortable using the contraceptive implant as a birth control method?	Yes/No

6.A.2 Underlying Algorithm Scoring

Each response to each question included in Table A1-1 may assign points in favor of a contraceptive method, or points against a contraceptive method. The underlying algorithm was developed by Melissa Kottke, MD, MPH and Robert Hatcher, MD, MPH at Emory University. An example of the algorithm decisions made in calculating a score for combined oral contraceptives is provided in Table A1-2.

Table A1-2. Example of algorithm scoring for combined oral contraceptives given responses to specific module questions

Variable Name	Response Option Chosen	Points	Comments
Q7 (smoker)	Less than daily (2) or Daily (3)	-999	
Q8 (regular period)	No (0)	+1	
Q8a (<3 periods/year)	Yes (1)	+1	
Q9 (heavy period)	Yes (1)	+1	
Q10 (period 7 days)	Yes (1)	+1	
Q11 (cramps)	Yes (1)	+1	
Q13 (depression)	Yes (1)	+1	
Q14 (bloating)	Yes (1)	+1	
Q16 (PMS)	Yes (1)	+1	
Q17 (miss school/work)	Sometimes (1) or Often (2)	+1	

Table A1-2, Continued

Variable Name	Response Option Chosen	Points	Comments
Q20bi_birthcontrol (unplanned pregnancy on OCP)	Yes (1)	-3	
Q20bi_miniPills (unplanned pregnancy on POP)	Yes (1)	-2	
Q21_birthcontrol (interested in OCP)	Yes (1)	+1	
Q21_miniPills (interested in POP)	Yes (1)	+1	
Q22ai_birthcontrol (currently using OCP)	Yes (1)	+1	
Q23ai_tender breasts	Yes (1)	-1	If on OCP, Ring
Q23ai_hairLoss	Yes (1)	-2	
Q23ai_depression	Yes (1)	-1	
Q23ai_nausea	Yes (1)	-1	
Q23ai_weightGain	Yes (1)	-1	
Q23ai_migraines	Yes (1)	-2	
Q23ai_noGetClinic	Yes (1)	-2	If on OCP, POP, Patch, Ring, Depo
Q23ai_noGetPharmacy	Yes (1)	-2	If on OCP, POP, Patch, Ring, Depo
Q23ai_expensive	Yes (1)	-1	
Q23ai_forgot	Yes (1)	-2	If on OCP, POP
Q23ai_noRestart	Yes (1)	-2	If on OCP, Patch
Q23ai_pregnant	Yes (1)		-3 (if on OCP); -2 (if on POP)
Q23ai_stroke	Yes (1)	-999	-999 if it occurs for ANY BC method
Q23ai_clot	Yes (1)	-999	
Q23ai_blood pressure	Yes (1)	-999	
Q23ai_prolonged bleeding	Yes (1)	-1	
Q23ai_prolonged bleeding	Yes (1)	+1	If on Depo, Paragard, Mirena, Implant
Q23ai_heavyBleed	Yes (1)	+1	If on Paragard, Mirena
Q23ai_irregularBleed	Yes (1)	-1	
Q23ai_irregularBleed	Yes (1)	+1	If on Depo, Paragard, Mirena, Implant
Q23ai_noBleed	Yes (1)	-1	
Q23ai_noBleed	Yes (1)	+1	If on Depo, Implant
Q23ai_partnerDislikes	Yes (1)	-1	
Q25_easyUse	Yes (1)	+1	
Q25_safeBreastFeeding	Yes (1)	-2	
Q25_cheap	Yes (1)	+1	
Q25_effective	Yes (1)	+1	

Note: *Score of -999 indicates medically contraindicated.*

6.A.3 End of Visit Survey

At the end of their clinical visit, participants completed an interviewer-administered survey that assessed their satisfaction with the computer module and the contraceptive method chosen. The contraceptive method choice as reported by the patient in the End-of-Visit survey was used

as outcome data for Hypothesis 1c and Hypothesis 2a. The question wording and response options for the End of Visit Survey are included in Table A1-3. Participants had the option of responding "I don't know" or "I prefer not to answer" to each question.

Table A1-3. End of Visit Survey: Question wording and response options

Question number	Question text	Response options
1	Which birth control method(s) did you get today?	None
		Patch
		Abstinence
		Withdrawal
		The pill
		Vaginal spermicides
		"Mini-pills" or progestin-only pills
		Rhythm method
		NuvaRing
		Tubal ligation
		Depo Provera
		Vasectomy
		Male condom
		Contraceptive implant
		Female barrier methods
		Breastfeeding
		EC
		IUD
2	Did you like using the computer to answer questions about birth control?	Yes/No
2a	Why not?	[Open text]
3	Did you have questions about your birth control choice that you wanted to ask the doctor or nurse, but did not?	Yes/No
4	After you answered the questions on the computer, did you think about using new or different birth control methods?	Yes/No

Table A1-3, Continued

Question number	Question text	Response options
5	How helpful was the printout for helping you choose a method of birth control?	
		Not at all helpful
		A little helpful
		Helpful
		Very helpful
6	Did you listen to the recorded voice when you used the computer?	Yes/No
6a	How much did the recorded voice help you understand the questions?	
		Not at all helpful
		A little helpful
		Helpful
		Very helpful
7	How often do you usually use a computer?	
		Every day
		Several times per week
		Once a week
		1-3 times per month
		Less than once per month
		Never

6.A.4 Translation of ACASI module and End of Visit Survey

The English wording of the questions and response options in the ACASI module and End of Visit Survey was developed by Emory University. Translation of the survey questions and response options was undertaken by Public Health Solutions, using a three-stage translation process. Two native Spanish-speaking translators were hired to independently translate the surveys. Translation versions were compared, and any discrepancies in translation were adjudicated by a third translator. The final translated version was reviewed by the original two translators for their approval. Then, the Spanish module was pilot tested with Spanish-speaking users to ensure comprehension, and feedback on wording was collected.

6.A.5 Clinical and administrative data

Informed consent included permission to link to clinical administrative data about the patient's visit. Clinical-administrative data included provider report of the contraceptive method chosen at the end of the visit (outcome data used for analyses testing Hypothesis 1a and 1b). Demographic information (age, parity, education, country of origin) was also extracted from the database. Other data exported from the clinical database included the results of behavioral and mental health risk screening, conducted as part of routine clinical care at the recruitment sites [209]. Behavioral and mental health screening results include symptoms of depression and/or anxiety (using the PHQ-4) [210, 211]; alcohol use (screening questions adapted from the AUDIT-C) [212, 213]; illicit drug use; cigarette smoking (using the 5 A's) [214]; and current or history of physical or sexual abuse.

6.B PATIENT INTERACTION WITH INTERVENTION

6.B.1 Patient Use of Intervention

The average time taken to complete the module was 16.5 minutes (standard deviation=8 minutes), and the median time was 15.2 minutes. The module offers the option of turning the audio on or off; about half (47%) reported using the audio, and 93% reported that the audio was helpful or very helpful in helping to understand the questions. Women who used the Spanish version were significantly more likely to report using the audio (56% compared to 37%, Chi-square $p<0.001$), as were women with less than a high school education ($p<0.001$), yet no differences in the reported usefulness of the audio were found by language or educational attainment. Figures A1-1 through Figures A1- 4 below provide visual examples of the module and the materials generated by the module.

Figure A1-1. Screen shot of contraceptive assessment module screen

Figure A1-2. Photograph of an individual interacting with module

Figure A1-3. Sample of tailored material (provided for Intervention + Tailored arm only)

Use this paper to talk to your health care provider about which birth control method is best for you.

Green = GO!

These are the birth control methods that fit your life and goals well and prevent pregnancy best.

Mirena Hormonal IUD (Intrauterine Device)

Para Gard Copper T IUD (Intrauterine Device)

The pill or birth control pills (containing both an estrogen and progestin)

Mini-Pills or progestin-only pills

Nuva Ring (the vaginal ring)

For extra protection no matter what method you choose, condoms and EC are available at this center:

Condoms can be used by themselves or with other birth control methods. Condoms can prevent pregnancy. Latex condoms can protect you from HIV and other sexually transmitted infections (STIs) like chlamydia, syphilis and gonorrhea. Use a new condom for each sex act.

If you forget to use birth control or your birth control method fails, ask your healthcare provider about **Emergency Contraception** (EC, also called Plan B). Emergency contraception is NOT a regular method of birth control. You have to take the EC pills starting within three days (72 hours) after having unprotected sex. Plan B is available over-the-counter for women age 18 and older. Plan B is available by prescription for women age 17 and younger.

Yellow = Slow!

These birth control methods are either less good at preventing pregnancy or may be a problem for you.

Depo Provera

Spermicide

Red = Stop!

These birth control methods are not the best for you because of your answers to the questions. They should not be used without careful discussion with your health care provider.

Vasectomy (sterilization for men)

Tubal ligation (sterilization for women)

Figure A1-4. Sample of generic material (provided for Intervention + Generic and Control arm)

Not all methods of birth control are the same in how well they prevent pregnancy. Also, not all methods of birth control are good for every woman. Talk to your health care provider about which birth control method is best for you.

Here is a list of birth control methods to discuss with your provider:
Birth control pills
Depo-Provera
Nuva Ring (the vaginal ring)
Paragard Copper T IUD (Intrauterine Device)
Mirena Hormonal IUD (Intrauterine Device)
Tubal ligation (sterilization for women)
Vasectomy (sterilization for men)
Emergency Contraception (EC or Plan B)
Diaphragm
Male condom
Female condom
Sponge
Spermicide
Fertility awareness method
Breastfeeding as a birth control method

For extra protection no matter what method you choose, condoms and EC are available at this center.

Condoms can prevent pregnancy. They act as a barrier by preventing the sperm from reaching the egg. Condoms can be used in combination with other birth control methods. Latex condoms can protect you from sexually transmitted infections (STIs) like HIV, chlamydia, syphilis and gonorrhea. To protect yourself from HIV and other STIs, use a new condom for each sex act.

If you forget to use birth control or your birth control method fails, ask your healthcare provider about Emergency Contraception (EC, also called Plan B). Emergency contraception is NOT a regular method of birth control. You have to take the EC pills starting within three days (72 hours) after having unprotected sex. Plan B is available over-the-counter for women aged 18 years and older. Plan B is available by prescription for women aged 17 years and younger.

6.B.2 Patient Satisfaction with Module

Almost all (99%) of participants – regardless of intervention arm – reported that they liked using the computer; among the 15% of participants who reported they never used a computer, 97% liked using the computer. In contrast with the findings in the primary outcome (Chapter 2, Tables 2-2a and 2-2b), participants' perception of the module did not differ by intervention arm: 86% of participants reported that the educational materials were helpful or very helpful, with no difference between those who got tailored or generic materials (p=0.176), and 29% across all arms reported thinking about using a new method after using the computer (p=0.081).

6.C ISSUES IN DATA COLLECTION SPECIFIC AIMS 1 & 2

6.C.1 Missing outcome data: Quality assurance activities to reduce missing data

At the time of initial export from the clinical-administrative database, a significant proportion of patients were missing data on the contraceptive method chosen at the time of visit: n=497 of the 2,448 in the intent-to-treat sample (20%); 138 of the 497 initially missing data were in the as-treated sample (n=1,983, a subset of intent-to-treat sample). Validation and medical record review was conducted by staff of the Clinical & Community Health Program at Public Health Solutions for all patients missing provider reported data on method choice.

After medical record abstraction, the number of participants missing data was reduced to 190 of the 2,448 the intent-to-treat sample (7.7%) This rate of missing data is still slightly higher than the FPAR annual rate (6%) reported in 2009 [215]. The proportion of patients in the intent-to-treat dataset who were missing outcome data in the clinical-administrative database did not differ significantly by randomization arm (p=0.1125) (discussed further in Appendix 2).

6.C.2 Reliability of outcome data sources: self report compared to clinical-administrative database

Given the issues discussed above, neither the self-report nor clinical-administrative data source can be considered a "gold standard." Reliability statistics were calculated for the two data sources of the same primary outcome, choosing an effective method of contraception. For the dichotomous primary outcome, in 94% of cases there was agreement between the clinical-administrative database and patient's self-report. Agreement beyond chance was excellent (Kappa = 0.838). Analyses for Specific Aim 1 included outcome data from both self-report and clinical-administrative sources to account for any systematic differences in reporting.

Patterns in disagreement between the provider and participant were evident. As shown in Table A1-3, agreement was high for some methods (generally, methods in the top two tiers of effectiveness), but particularly low for condoms (50%) and no method (66%). Because participants in the Control arm, compared to those in the Intervention + Tailored and Intervention + Generic arms, were significantly more likely to choose either no method or condoms only, disagreement was more likely to occur among Control participants.

Table A1-4. Agreement of provider- and self-reported contraceptive method choice, by provider-reported method, for the most commonly reported methods, in as-treated sample

					Of disagreed	
Method listed in clinical-administrative database	**n**	**Agreed, %**	**Agreed, n**	**Disagree, n**	**Patient reported less effective method**	**Patient reported more effective method**
Pill	698	97%	679	19	15	4
IUD	436	88%	384	52	52	0
Male Condom	338	50%	168	170	141	29
DepoProvera	198	95%	188	10	10	0
No Method	138	66%	91	47	0	47
NuvaRing	69	99%	68	1	1	0

For some methods, discrepancies between the patient and provider report may be attributed to potentially confusing wording of the question on the End of Visit Survey, “Which method did you get today?” For example, patients who already had an intrauterine device inserted prior to the clinical visit may not have felt that they actually “got” a method at the visit. This hypothesis was supported by a chart audit of instances where the provider reported choice of IUD and the patient reported choosing no method that revealed documentation in the medical record suggesting that 97% of these patients had an IUD inserted prior to or on the date of visit.

6.C.3 Health literacy and comprehension of questions

The intervention, in integrating touchscreen and ACASI technology, was designed to be used by women of all literacy levels. All of the questions in the ACASI module are read aloud, and each answer is highlighted on screen as it is read aloud. No reading is required, therefore, to interact with the module. Health literacy, however, is more than reading ability; limited functional health literacy also affects numeracy and oral communication [137]. Literacy levels of participants was not directly assessed; educational attainment was used as a proxy measure of literacy level.

The results of some analyses suggest that, despite efforts to make the intervention accessible for women of all literacy levels, some participants may have faced literacy challenges. Women who did not complete participation in the intervention or control condition and data collection on the day of their family planning visit were significantly more likely to have lower educational attainment, to have used the Spanish version of the module, and to be foreign-born.

Responses to specific questions also suggest that comprehension may have been a barrier for a subset of participants. After frequency analyses revealed that more than 10 percent of teen (age 16-19) module users in the as-treated analysis (n=216) responded to Q26

("How often do you want to actively do something for your birth control?") that they would be interested in permanent methods of birth control, responses to Q24 ("How soon do you want to get pregnant?") were cross-tabulated with responses to Q26 for all module users in the as-treated sample (n=1,484). A total of 204 participants (13.7% of module users in the as-treated sample) responded that they were interested in a permanent method of contraception, but reported that they wanted to become pregnant at a time point other than "never." Women who used the Spanish version of the module were significantly more likely to give this contradictory response pattern compared to users of the module in English (19% versus 7%, Chi-square test $p<0.001$), as were women who were foreign-born (16% versus 6%, $p<0.001$), but no differences by educational attainment were detected (Chi-square $p=0.949$).

6.C.4 Missing independent variables from ACASI module (intervention or control condition)

One of the benefits of ACASI as an interviewing technique is that missing data are not due to interviewer error. Data, however, can still be missing: the ACASI module allowed participants to choose "I don't know" or "I don't want to answer" for each question. The average number of questions not answered was less than one (0.76), and the number of skipped questions ranged from 0 to 25. Because control group participants were only asked 10 of the questions in the module while those in the Intervention + Tailored and Intervention + Generic were asked 50 or more questions, the number of questions not answered by participants differed significantly by randomization arm (ANOVA $p<0.001$). Only 21 participants (1.4% of the as-treated sample) skipped 10 or more questions.

Among the module users in the as-treated sample (n=1,484), the proportion of patients skipping 10 or more questions did not differ significantly by the primary outcome (Chi-square test $p=1.000$), by the randomization arm (Chi-square test $p=1.000$), or by any of the sociodemographic characteristics listed in Table 1 of Chapter 2 (all Chi-square test p-values >

0.05), with the exception of computer usage. Module users who reported that they never use the computer (n=232, or 16% of the module users) were significantly more likely than those use the computer infrequently (more frequently than never, but not everyday) or frequently (once a week or daily) to skip 10 or more questions: 5.2%, 1.2% and 0.7%, respectively (Chi-square test $p<0.001$).

Some questions in the module were more frequently skipped by respondents than others. Only three questions in the entire module were skipped by more than 3% of the as-treated sample (n=1,983). The most commonly skipped question was asked the respondent's weight (Table A1-1, Q3), with 5% (n=99) of participants in the as-treated sample responding "don't know" and another 0.5% (n=10) indicating "don't want to answer." The question inquiring about what contraceptive methods the participant was interested in (Table A1-1, Q21) required participants to view contraceptive methods listed on three successive screens. On the first screen of Q21, 3.1% (n=62) responded "don't know" and 0.8% (n=15) responded "don't want to answer" By the third screen, Q21 was not completely responded by 123 participants (n=91 (4.6%) as "don't know" and n=32 (1.6%) as "don't want to answer"). These response patterns suggest that, in future versions of the module, questions should not repeat across many screens when possible. Finally, the question (Q26) asking, "How often do you want to actively do something for your birth control?" may not have been well understood by participants: 4% (n=82) responded "don't know" and 1.2% (n=24) responded "don't want to answer." Future versions of the module should consider using a re-worded version of this question.

6.C.5 Missing data on contraceptive method used at start of visit

The question that asked about contraceptive method use at the start of the visit (Table A1-1, Q22ai) was not answered by all module users; the question listed all possible contraceptive methods across three computer screens, and participants could choose as many methods as they were currently using. Of the 1,454 module users included in the analyses for Chapter 3, 27

(1.9%) reported that they were using more than one hormonal contraceptive method, 33 (2.3%) did not see all of the screens of the question, 7 (0.5) did not want to answer the question, and 9 (0.6) responded that they did not know. These 76 participants were excluded from Table 3-3 in Chapter 3.

6.C.6 Reliability of Module independent variable data

6.C.6.a Age

Age was one of the few variables available in the administrative data record that was also available in the ACASI module. In the as-treated (n=1,983) sample, 1,938 (98%) participants responded with their age to the ACASI module. For this group, the correlation between self-reported age and the age reported in the administrative database was 0.956 ($p<0.001$). After logic checks and cleaning, excluding any self-reported ages outside the range of 16 through 50 to account for entry errors by participants (n=1,882), the correlation was 0.993 ($p<0.001$). In final analyses, a recoded age was used: the self-reported age was used if the response was within logical ranges (16 through 50). If the self-reported age was missing or outside the logical range, the age recorded in the administrative database was used.

6.C.6.b Race, ethnicity, birthplace & module language

For descriptive analyses, responses to Q4 in the module, a question to which multiple answers were allowed ("What is your race or ethnicity?"), ethnicity and race was recoded into a three-level variable: Latina, of any race; Non-Latina black; Non-Latina other race. To gauge the reliability of the recoded self-reported ethnicity, cross-tabulations were made of the recoded ethnicity groups with the module language and birthplace (US/foreign born) using the as-treated (n=1,983) sample. No participants in the as-treated sample who identified themselves as non-

Latina chose to use the module in Spanish. Of the 1,104 participants in the as-treated sample who used the module in Spanish, only 1% (n=12) reported that they had been born in the US.

7 APPENDIX 2: SUPPORTING ANALYSES FOR CHAPTER 2

7.A OPERATIONALIZATION OF PRIMARY OUTCOME

7.A.1 Operationalization of primary outcome for Specific Aim 1

The operationalization of the primary outcome for Specific Aim 1 analyses presents some potential problems. The potential problems, and the number of subjects affected in each analysis, are summarized in Table A2-1. The clinical-administrative data issues summarized here are the data after quality assurance and validation (Appendix 1, Section 6.C.1.).

Table A2-1. Potential problems with operationalization of choice of an effective method outcome

Issue	Intent-to-Treat, Clinical-administrative report n=2,448	As-treated, self-report n=1,983	As-treated, Clinical-administrative report n=1,983
Abstinence only	27	1	26
Dual method use	17	11	17
Emergency contraception only	0	14	0
Pregnant or seeking pregnancy	20	0	18
Missing data	190	1	23

Notes: *Issues are mutually exclusive. Dual method use does not include participants who reported receiving emergency contraception and a method of contraception.*
Patients who were pregnant or seeking pregnancy were coded as using no method.
Patients who reported abstinence were excluded from analyses

7.A.2 Abstinence only

Abstinence has not been categorized by the WHO because of a lack of effectiveness data on typical use (rather than perfect use); therefore, women who reported choosing abstinence were excluded from analyses testing Specific Aim 1 hypotheses. As shown in Table A2-2, only 1 participant in the as-treated analysis reported choosing abstinence. The self-reported method choice of the 27 participants who were coded in the clinical-administrative database as choosing abstinence is listed in Table A2-3. As shown, 89% of the 27 patients who were listed in the

clinical-administrative database reported they chose no method, although abstinence was included as a response option in the End of Visit Survey (Table A1-1).

Table A2-2. Self-reported method choice of women in the intent-to-treat dataset using clinical-administrative data as choosing abstinence (n=27)

Self-reported method choice	Frequency (n)
None	24
Male condom	2
Female barrier method and emergency contraception	1

7.A.3 Dual methods

For women who reported choosing more than one method, method effectiveness was categorized according to the more effective method, consistent with analyses for the National Survey of Family Growth [32]. In the as-treated sample with self-report, only 11 participants reported dual method choice; 10 of these women reported condoms with another method, and one reported a dual-method choice that suggested possible data error (combined oral contraceptives and Depo-Provera). This classification would underestimate condom use across the board, but would not bias findings of differences across randomization arms [71]. In the as-treated sample using clinical-administrative outcome data, 16 of the 17 patients who were coded as choosing more than one method had condoms and another method recorded; the other patient in this dataset had dual-method choice that indicated possible data error (Depo-Provera and IUD). This data error would not misclassify the choice using the dichotomous outcome, as both methods are effective methods.

7.A.4 Emergency contraception

Emergency contraception is offered to all family planning patients at the centers as part of standard of care. Patients who reported receiving only emergency contraception on the da of their visit were coded as choosing no contraceptive method. Women who reported receiving

emergency contraception and a method of contraception were not coded as choosing dual methods; they were coded only as receiving the reported method of contraception.

7.A.5 Pregnancy or seeking pregnancy

Patients who were pregnant or seeking pregnancy were not eligible to participate in the study. Participants were screened for eligibility before the consent process. Nevertheless, in the as-treated sample, 18 patients had outcome data in the clinical-administrative data that indicated they chose no method because they were pregnant (n=1) or seeking pregnancy (n=17). Analyses relying on clinical-administrative outcome data coded these 20 participants as choosing no method.

Validation of provider report in the clinical-administrative database of pregnancy or seeking pregnancy was conducted by examining the participants' responses to module Q24 ("How soon do you want to get pregnant?"), listed in Table A2-3. No participants reported they wanted to get pregnant in less than a year, suggesting poor validity of the provider report.

Table A2-3. Self-reported pregnancy intention status of participants in the as-treated sample, listed in clinical-administrative database as pregnant or seeking pregnancy (n=18)

Response to "How soon do you want to get pregnant?"	**Frequency (n)**
Less than one year	0
In one to three years	6
In three or more years	2
Not sure when but definitely want to have a baby	6
Never	4

7.B ANALYSES TO TEST HYPOTHESES

7.B.1 Contraceptive method choice, using categorical outcome

Analyses of Specific Aim 1, presented in Chapter 2, used a dichotomous primary outcome. Contraceptive method effectiveness was also modeled as a categorical variable, based on typical use effectiveness rates, as shown in Table A2-4.

Table A2-4. Categorical operationalization of contraceptive method effectiveness

Contraceptive method	Proportion of women experiencing unintended pregnancy in 1 year, typical use [73, 147]	Categorized outcome (WHO Effectiveness Tier)
IUD (Mirena)	0.1	1
Vasectomy/male sterilization	0.15	1
Implant (Implanon)	0.2	1
Tubal ligation/female sterilization	0.5	1
IUD (Copper T/Paragard)	0.8	1
Injectable (Depo-Provera)	3	2
Pills (combined, progestin-only), Ring (NuvaRing), Patch (OrthoEvra)	8	2
Female condom	21	3
Male condom	15	3
Diaphragm	16	3
Periodic abstinence	25	3
Withdrawal	27	4
Spermicide	29	4
No method	85	None

Using the WHO categorization of effectiveness tiers [102], the results for unstratified analyses also showed a significant effect of the module on contraceptive method choice (Figure A2-1): participants who used the module, compared to those in the control group, were significantly more likely to choose a method in the top tier of effectiveness and less likely to choose no method (Chi-square $p<0.001$). No patients chose a method in the lowest effectiveness tier (Tier 4) (withdrawal or spermicide used alone).

7.B.2 Contraceptive method choice, by specific method

The specific contraceptive method chosen by participants was assessed by randomization arm. As shown in Table A2-5, the results were consistent with the findings using a dichotomous outcome and a categorical outcome.

Table A2-5. Contraceptive methods chosen in as-treated sample, by randomization arm (n=1,983)

	Intervention + Tailored (n=834)		Intervention + Generic (n=650)		Control (n=499)	
	n	**%**	**n**	**%**	**n**	**%**
Vasectomy	1	0%	0	0%	0	0%
IUD	184	22%	156	24%	74	15%
Depo-Provera	79	9%	72	11%	52	10%
Patch	2	0%	7	1%	6	1%
NuvaRing	35	4%	22	3%	17	3%
Combined oral contraceptives	307	37%	233	36%	151	30%
Progestin-only pills	3	0%	5	1%	2	0%
Female barrier methods	1	0%	2	0%	4	1%
Male condoms	87	10%	55	8%	72	14%
Periodic abstinence	2	0%	0	0%	0	0%
Abstinence	0	0%	0	0%	1	0%
Emergency contraception	2	0%	8	1%	4	1%
No method	131	16%	90	14%	116	23%

Note: *Participants who reported choosing more than one method were categorized as choosing the more effective method.*

7.B.3 Subgroup analyses among patients not using contraception at start of visit

Recognizing that some family planning patients may choose the same method of contraception at the end of their visit that they had been using at the start of their visit, and that these methods of contraception may be effective methods, a more meaningful assessment of the impact of the intervention may be among non-users of contraception. Therefore, the primary outcome analysis testing the hypothesis of Specific Aim 1 was repeated among the subset of participants who were non-users of contraception at the start of their visit. Full data on contraceptive method choice at the start of visit is not available for participants who did not complete participation; therefore, intent-to-treat analyses could not be conducted. The proportion of participants in the as-treated sample who were using no method of contraception at the start of the visit (45%) did not differ significantly across randomization arms (Chi-square test p=0.08).

As shown in Table A2-6, among participants who were not using contraception at the start of their visit, those who used the module, compared to the control group, were significantly more likely to choose an effective method of contraception.

Table A2-6. As-treated logistic regression models of choosing an effective contraceptive method, by outcome data source, adjusted for site of recruitment, among participants who were using no method of contraception at the start of their visit (n=888)

	As-treated, clinical-administrative outcome data (n=835)			As-treated, patient self-report outcome data (n=888)		
Randomization arm	**n**	**Chose effective method**		**n**	**Chose effective method**	
		%	**OR (95%CI)**		**%**	**OR (95%CI)**
Intervention + Tailored	355	63%	1.69 (1.20-2.38) p=0.003	377	60%	1.64 (1.18-2.29) p=0.003
Intervention + Generic	258	63%	1.67 (1.16-2.42) p=0.006	270	63%	1.87 (1.31-2.68) p=0.001
Control [Ref.]	222	50%	---	241	47%	---

Note: *Adjusted for clinical site of recruitment. The proportion of participants in this sample who were missing clinical-administrative data on contraceptive method choice (6%) is similar to that of the overall sample (7%).*

The specific contraceptive method choice of participants was examined among the participants in the as-treated sample who were using no contraception at the start of their visit (n=888). As shown in Table A2-7, 14% of the new users of contraception in the Intervention + Tailored arm chose IUDs, compared to 19% in the Intervention + Generic arm, and 7% in the Control arm. More analyses of the shifts in contraceptive method from the start of the visit to the end of the visit among participants in the two Intervention arms are presented in Chapter 3, Table 3-2.

Table A2-7. Contraceptive methods chosen among participants in as-treated sample who were using no method of contraception at the start of their visit, by randomization arm (n=888)

	Intervention + Tailored (n=377)		Intervention + Generic (n=270)		Control (n=241)	
	n	%	n	%	n	%
Vasectomy	1	0%	0	0%	0	0%
IUD	53	14%	51	19%	18	7%
Depo-Provera	29	8%	25	9%	20	8%
Patch	0	0%	3	1%	4	2%
NuvaRing	9	2%	4	1%	10	4%
Combined oral contraceptives	134	36%	86	32%	59	24%
Progestin-only pills	1	0%	2	1%	1	0%
Female barrier methods	0	0%	1	0%	4	2%
Male condoms	53	14%	29	11%	42	17%
Periodic abstinence	2	1%	0	0%	0	0%
Abstinence	0	0%	0	0%	1	0%
Emergency contraception	2	1%	5	2%	3	1%
No method	93	25%	64	24%	79	33%

Note: *Participants who reported choosing more than one method were categorized as choosing the more effective method.*

7.C ANALYSES TO ADDRESS POTENTIAL SOURCES OF BIAS

7.C.1 Confounding by Recruitment Site

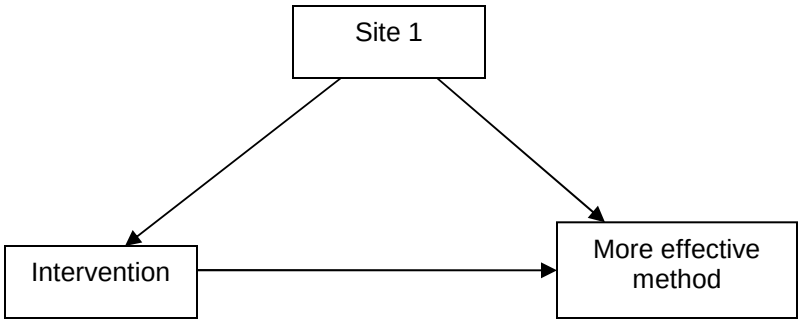
Because of the shift in the randomization allocation after recruitment, a larger proportion of control patients were recruited at the clinical site with the larger patient population (Site 2). Because patients at Site 1 were more likely to be randomized to one of the Intervention arms (Intervention + Tailored or Intervention + Generic) (Chi-square test $p<0.001$, as shown in Table 2-1), and were more likely to choose an effective contraceptive method (Table A2-8), the recruitment site can be considered a positive confounder (Figure A2-2). As would be expected, the main findings for the intent-to-treat analyses moved closer to the null after adjustment for the recruitment site (for Intervention + Tailored, the OR was attenuated from 1.65 to 1.56 after adjustment; for Intervention + Generic, the OR was attenuated from 1.86 to 1.74).

Table A2-8. Logistic regression models of choosing an effective method, by recruitment site, randomization arm, and both recruitment site and randomization arm, intent-to-treat sample (n=2,231)

	Site Only	Randomization Arm Only	Randomization Arm, Adjusted for Site
Randomization Arm	**OR (95%CI)**	**OR (95%CI)**	**OR (95%CI)**
Intervention + Tailored (n=985)	---	1.65 (1.31-2.09) p<0.001	1.56 (1.23-1.98) p<0.001
Intervention + Generic (n=756)	---	1.86 (0.45-2.40) p<0.001	1.74 (1.35-2.25) p<0.001
Control (n=490)	---	[Ref.]	[Ref.]
Recruitment Site	**OR (95%CI)**	**OR (95%CI)**	**OR (95%CI)**
Site 1 (n=1,355)	1.47 (1.22-1.78) p<0.001	---	1.37 (1.12-1.66) p=0.002
Site 2 (n=876)	[Ref.]	---	[Ref.]

Note: *27 patients who reported choosing abstinence were excluded because no typical-use effectiveness data are available; 190 patients missing outcome data from clinical-administrative database.*

Figure A2- 2. Directed acyclic graph of confounding by recruitment site



The main findings for Specific Aim 1 analyses, outlined in Chapter 2, presented logistic regression models that adjusted for clinical site of recruitment to control for confounding by clinical site. The intent-to-treat analyses were repeated, analyzing the result at each recruitment site separately. As shown in Table A2-9, separating the two sites resulted in a non-significant finding at the smaller of the two clinical sites (Site 2, with only 876 participants in the intent-to-treat sample).

Table A2-9. Intent-to-treat logistic regression models of choosing an effective contraceptive method, comparing a model adjusting for clinical site to findings stratified by clinical site

	Both sites, adjusted for clinical site (n=2,231)	**Site 1 (n=1,355)**	**Site 2 (n=876)**
Randomization arm	**OR (95%CI)**	**OR (95%CI)**	**OR (95%CI)**
Intervention + Tailored	1.56 (1.23-1.98) p<0.001	1.93 (1.38-2.70) p<0.001	1.29 (0.92-1.80) p=0.144
Intervention + Generic	1.74 (1.35-2.25) p<0.001	2.13 (1.50-3.03) p<0.001	1.45 (0.99-2.10) p=0.054
Control [Ref.]	---	---	---

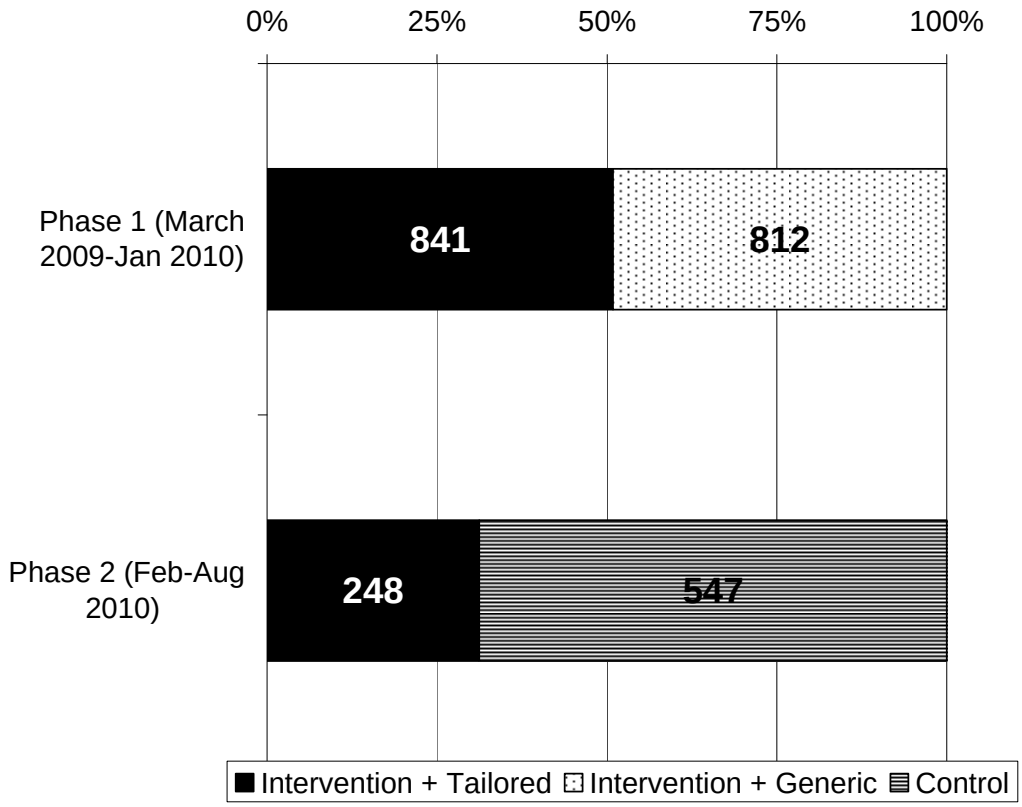
Note: *27 patients who reported choosing abstinence were excluded because no typical-use effectiveness data are available; 190 patients missing outcome data from clinical-administrative database.*

Statistical power may have hampered analyses testing the impact of the intervention at the smaller site (Site 2). These analyses were repeated for Site 2, combining the two Intervention arms. Findings were of borderline statistical significance (OR=1.35, 95%CI: 0.99-1.83, p=0.056).

7.C.2 Confounding by Time

Participant recruitment took place over a period of 18 months. Controls were recruited in later time periods, as shown in Figure A2-3. Time-related changes may affect the later-recruited participants (who were predominantly controls) differently from those recruited earlier.

Figure A2-3. Number of participants recruited and randomized in each recruitment phase, Intent-to-Treat sample (n=2,448)



There were some changes in the availability of specific contraceptive methods at the centers (Mirena IUDs were not stocked by the center formulary for a period at the end of patient recruitment). This directly affects both the primary exposure (intervention arm) and the Specific Aim 1 primary outcome (contraceptive method choice).

Mirena IUDs were not stocked by the formulary at the two clinical sites for a period at the end of patient recruitment. At site 1, the last Mirena insertion was on March 24, 2010, and at site 2, the last Mirena insertion was February 23, 2010. While Mirena IUDs may have been available at the center after these last insertion dates, analyses were conducted under conservative assumptions that they were not available. Intent-to-treat analyses with clinical-

administrative outcome data were repeated for two time periods: after the addition of the control arm (February 1, 2010), but before the respective last Mirena insertion date at the two sites; and after the last Mirena insertion date at the respective sites to the end of participant recruitment (August 2010). During this phase of recruitment, participants were randomized only to the Intervention + Tailored and Control groups. The main intent-to-treat analysis comparing the primary outcome across randomization arms, adjusting for clinical site, was repeated for these two time periods separately. As shown in Table A2-10, while the point estimates for the odds ratio were above the null, the confidence intervals were wide and included 1.0. In both time periods, the proportion choosing effective methods in the Intervention + Tailored group was sizably higher than among those in the Control group, but the Chi-square tests were not significant, indicating that these analyses are statistically underpowered. The proportion of controls choosing an effective method was the same (or marginally higher) in these later time periods as in the entire time period (66%, compared to 65%).

Table A2-10. Intent-to-treat logistic regression analyses of choosing an effective method: entire time period, and in later time periods defined by addition of control arm and Mirena availability

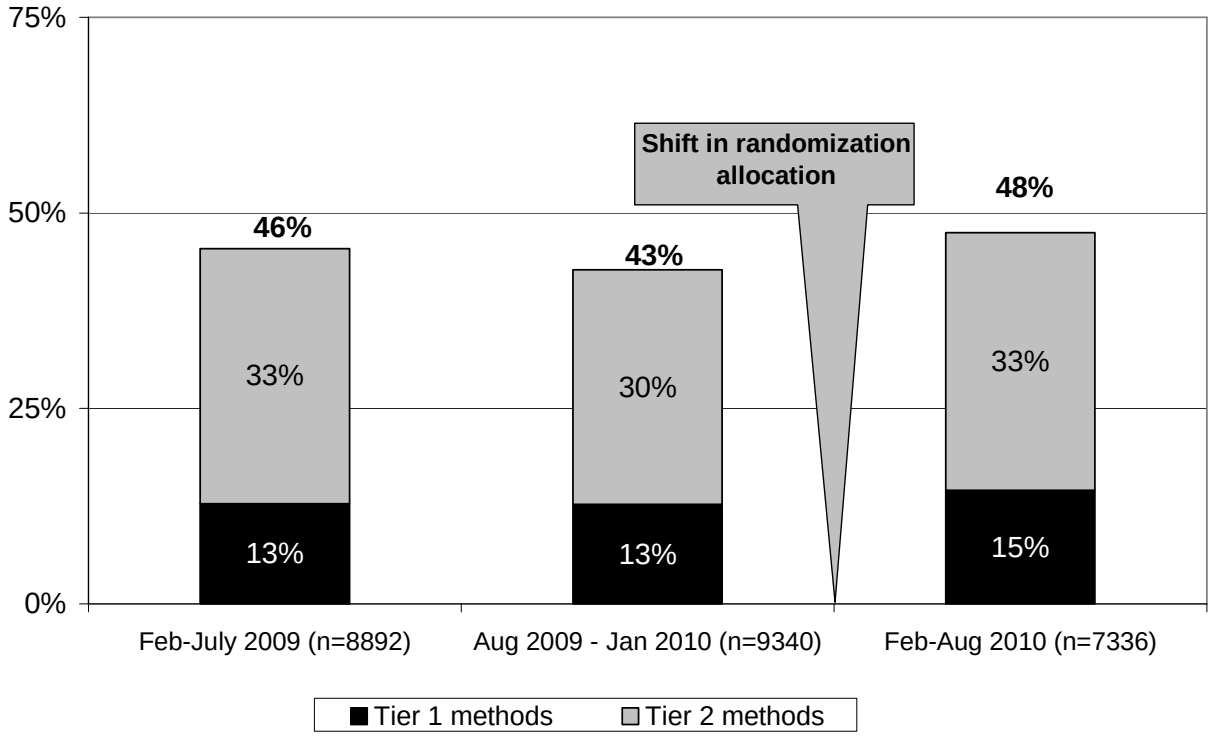
	Chose an effective method				
	Proportion			**Logistic regression model***	
Time Period	**Intervention + Tailored**	**Control [Ref.]**	**Chi square p-value**	**OR**	**95% CI**
All randomized (n=2,231)	75%	65%	p<0.001	1.56	(1.23-1.98)
After controls added until last Mirena insertion (n=126)	73%	66%	p=0.197	1.78	(0.77-4.13)
After last Mirena insertion until end of recruitment (n=416)	76%	66%	p=0.314	1.36	(0.85-2.16)

Note: *Logistic regression model adjusted for clinical site*

An examination of contraceptive method choice patterns across the clinical network further suggests that time-related change is not an alternative explanation for the observed findings. Patients in the control group were more likely to be recruited in later time periods. In the third

tertile of participant recruitment when controls were recruited (February through August 2010), effective methods (Tier 1 and Tier 2 methods, using categorization outlined in Table A2-1) were more available and more widely prescribed within the network (Figure A2-4). Controls therefore had better access to effective methods than participants recruited earlier, which would suggest that time-related factors, if a source of bias, would bias findings toward, not away, from the null.

Figure A2-4. Prevalence of effective contraceptive methods at clinical network, by time period of recruitment



7.C.3 Self-Selection Bias: Results from Refusal Survey

In order to ensure that the family planning patients who consented to participate in the trial were drawn from the general source population of the family planning patients at the site, a brief survey was conducted among patients who declined participation in the trial. This refusal survey was reviewed and approved by the Institutional Review Board of Public Health Solutions.

Of the 108 patients approached for the refusal survey, 91 (84%) gave consent to respond to the 4-question anonymous survey. Of the 91 respondents in the refusal survey, the average age was 29.7 (range: 17 to 48), slightly older than the average age of those who consented and completed participation (27.7); 65% spoke Spanish (compared to 58.6% of those who consented to participate); and half (45 of 89 participants who answered a question about frequency of computer use) reported they never used the computer. While the sample size for the refusal survey is small, patients who gave consent to participate in the trial may have more computer experience than those who declined participation. Among those who completed participation in the intervention or control condition and data collection on the day of their visit, 15% reported they never used a computer. The computer use experience of participants who consented to participate but who did not complete participation in the intervention or control condition and data collection on the day of visit is unknown. While this affects external validity, differences in computer use are not expected to be related to contraceptive method choice, and are therefore not considered a potential source of bias in the analyses.

7.C.4 Selection bias due to Non-Completion on Day of visit

As discussed in Chapter 2, participants randomized to the Intervention + Tailored and Intervention + Generic arms were more likely to not complete participation and data collection on the day of their family planning visit (23% and 20%, respectively) than those randomized to the control arm (9%). If, as shown in Figure A2-5, those who do not complete participation have a different probability of the outcome (choice of an effective contraceptive method), due to a characteristic either measured or unmeasured, this could be a source of bias [216].

Comparison of the intent-to-treat and as-treated analyses using the same data source for outcome data, presented in Table A2-11, suggests that selection bias due to non-completion on the day of the family planning visit was not a source of bias in the study.

Figure A2-5. Directed acyclic graph of selection bias due to non-completion

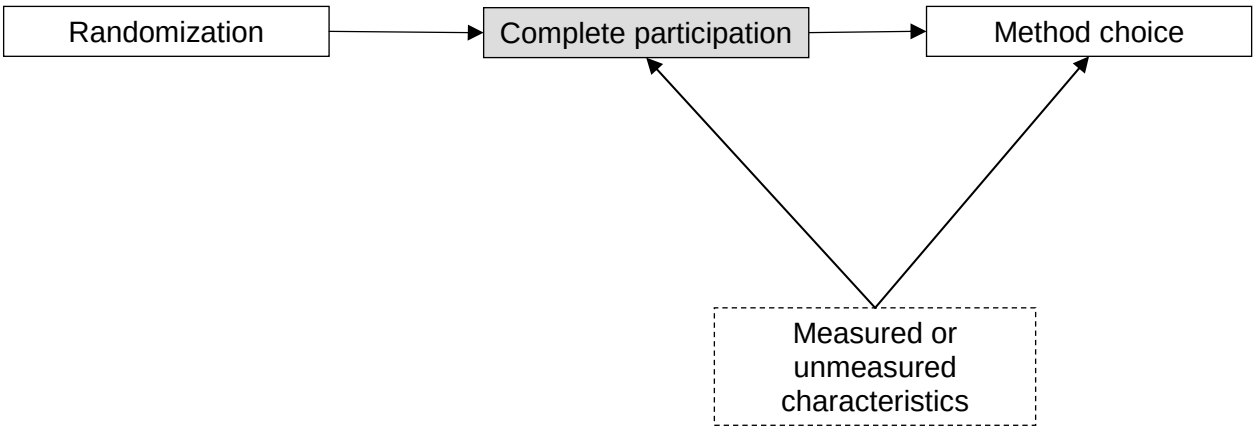


Table A2-11. Comparison of intent-to-treat and as-treated logistic regression models of choosing an effective contraceptive method, comparing each intervention arm to control condition, adjusted for site of recruitment

	Intent-to-Treat n=2,231			As-treated n=1,934		
Randomization arm	**n**	**Chose effective method**	**OR (95%CI)**	**n**	**Chose effective method**	**OR (95%CI)**
Intervention + Tailored	985	75%	1.56 (1.23-1.98) p<0.001	815	76%	1.55 (1.21-1.99) p=0.001
Intervention + Generic	756	78%	1.74 (1.35-2.25) p<0.001	637	76%	1.56 (1.21-2.04) p=0.001
Control [Ref.]	490	65%	---	482	66%	---

Note: *Adjusted for clinical site of recruitment. Patients who reported choosing abstinence were excluded because no typical-use effectiveness data are available: 27 in intent-to-treat; 1 in as-treated patient report; 26 in as-treated, clinical-administrative report.*

7.C.5 Information Bias: Missing Data

7.C.6 Missing outcome data in Intent-to-Treat analyses, clinical-administrative data

Of the 2,448 participants randomized and included in the intent-to-treat analyses, 190 (7.7%) were missing outcome data (contraceptive method choice) in the clinical-administrative

database. As shown in Table A2-12, the proportion of participants missing data did not differ significantly by randomization arm.

Table A2-12. Proportion of intent-to-treat sample missing outcome data from clinical-administrative database (n=2,448)

	Intervention + Tailored (n=1,090)	Intervention + Generic (n=812)	Control (n=546)
N missing data	93	50	47
%	8.5%	6.2%	8.6%

Note: *Chi square test = 4.368; p=0.1125*

7.C.7 Sensitivity analyses of Intent-to-Treat analysis under various assumptions

As discussed in Chapter 2, the intent-to-treat analyses were subjected to sensitivity analyses under a range of assumptions about the distribution of the outcome for the n=190 participants missing outcome data from the clinical administrative database. First, the most possible conservative assumptions were tested. The most conservative assumptions were that:

- All abstinent (n=27) chose no method;
- All Intervention + Tailored group participants with missing data (n=93) chose less effective/no method;
- All Intervention + Generic group participants with missing data (n=50) chose less effective/no method; and
- All Control group participants with missing data (n=47) chose an effective method.

More reasonable, but still conservative assumptions were then tested. The more reasonable assumptions made were that:

- All abstinent (n=27) chose no method;

- Among Intervention + Tailored group participants with missing data (n=93), 65% (n=60) chose an effective method, a proportion 10 percentage points lower than in available data;

- Among Intervention + Generic group participants with missing data (n=50), 68% (n=34) chose an effective method, a proportion 10 percentage points lower than in available data, and the remaining chose a less effective or no method; and

- Among Control group participants with missing data (n=47), 75% (n=35) chose an effective method, a proportion 10 percentage points higher than in available data, and the remaining chose a less effective or no method.

The distribution of the outcome and randomization arm in the analysis after applying these assumptions is presented in Table A2-13.

Table A2-13. Distribution of randomization arm and primary outcome for those missing clinical administrative data, under reasonable conservative assumptions, to inform sensitivity analysis of intent-to-treat analysis (n=190)

Chose effective method	Intervention + Tailored	Intervention + Generic	Control	Total
No	33	16	12	61
Yes	60	34	35	129
Total	93	50	47	190

In sensitivity analyses using conservative but reasonable assumptions, presented in Table A2-14, module users (Intervention + Tailored and Intervention + Generic) remained significantly more likely to choose an effective method of contraception compared to those randomized to the control arm.

Table A2-14. Results of sensitivity analyses of intent-to-treat findings, under most conservative and conservative but reasonable assumptions (n=2,448)

	Available data n=2,231		**Most conservative assumptions n=2,448**		**Conservative but reasonable assumptions n=2,448**	
	Chose an effective method		**Chose an effective method**		**Chose an effective method**	
Randomization arm	%	OR (95%CI)	%	OR (95%CI)	%	OR (95%CI)
Intervention + Tailored	75%	1.56 (1.23-1.98) p<0.001	72%	1.00 (0.80-1.25) p=0.986	74%	1.40 (1.11-1.75) p=0.004
Intervention + Generic	78%	1.74 (1.35-2.25) p<0.001	68%	1.20 (0.94-1.52) p=0.138	76%	1.58 (1.24-2.02) p<0.001
Control [Ref.]	65%	---	67%	---	65%	---

Note: *Analyses adjusted for recruitment site*

7.D ADDITIONAL ANALYSES

7.D.1 Tests for Statistical Interaction

7.D.1.a Language of module

Among those in the intent-to-treat dataset (2,448), 59% (n=1,434) used the module in Spanish. Tests for statistical interaction of the intervention with Spanish language use of the module were conducted. To increase statistical power, and because no significant difference in the primary outcome was found between the two intervention arms, the Intervention + Tailored and Intervention + Generic groups were combined for these analyses. No interaction effect for Spanish module users (n=1,434) in a relative risk regression model adjusted for clinical site (p=0.201), as shown in Table A2-15.

Table A2-15. Test of statistical interaction of module with language of module (Spanish/English), in intent-to-treat sample, relative risk regression adjusting by clinical site (n=2,231)

			95% CI	
	p-value	**RR**	**Lower**	**Upper**
Any Intervention Group	.001	1.22	1.08	1.37
Spanish Module	.003	1.22	1.07	1.40
Spanish*Intervention Interaction	.201	0.91	0.78	1.05
Clinical Site 1	.029	1.06	1.01	1.11

7.D.1.b Young age (16 through 24)

Tests for statistical interaction of the intervention with age were conducted, again combining the two intervention groups (Table A2-16). Of the 2,380 participants with available age data in the intent-to-treat dataset (age was missing for n=68), 830 (35%) were age 16 through 24. No significant statistical interaction between the intervention and younger age was found in the relative risk regression model (p=0.495).

Table A2-16. Test of statistical interaction of module with young age (16-24), in intent-to-treat sample, relative risk regression adjusting by clinical site (n=2,231)

			95% CI	
	p-value	**RR**	**Lower**	**Upper**
Any Intervention Group	<.001	1.17	1.07	1.28
Age 16- 24	.804	0.98	0.86	1.12
Age 16-24 * Intervention Interaction	.495	0.95	0.82	1.10
Clinical Site 1	.004	1.08	1.02	1.14

7.D.1.c Clinical Site

Tests for statistical interaction of the intervention with the clinical site of recruitment were conducted, again combining the two intervention groups (Table A2-17). In a relative risk regression model, no statistical interaction between the intervention and clinical site was observed (p=0.184).

Table A2-17. Test of statistical interaction of module with clinical site of recruitment, in intent-to-treat sample, relative risk regression (n=2,231)

	p-value	RR	95% CI	
			Lower	Upper
Any Intervention Group	.066	1.10	0.99	1.22
Clinical Site 1	.913	1.01	0.88	1.15
Clinical Site * Intervention Interaction	.184	1.10	0.95	1.27

7.D.1.d Contraceptive Use Status at Start of Visit

At the start of the visit, 43% (n=1,031) of the intent-to-treat sample was using no method of contraception. A test of statistical interaction between the intervention and contraceptive use status was conducted, combining the two intervention groups (Table A2-18). In a relative risk regression model adjusting for clinical site of recruitment, the test was of borderline statistical significance (p=0.056). The implication of this finding is discussed in Chapter 5.

Table A2-18. Test of statistical interaction of module with contraceptive use status at start of visit, in intent-to-treat sample, relative risk regression adjusting for clinical site of recruitment (n=2,231)

	p-value	RR	95% CI	
			Lower	Upper
Any Intervention Group	.081	1.06	0.99	1.14
Using no contraception at start of visit	<.001	0.61	0.53	0.71
Using no contraception at start of visit * Intervention Interaction	.056	1.17	0.99	1.37
Clinical Site 1	.111	1.04	0.99	1.10

7.D.1.e Birthplace

In the intent-to-treat sample, 77% (n=1,924) were born outside the United States. A test for statistical interaction of the intervention with birthplace was conducted, combining the two intervention groups (Table A2-19). In a relative risk regression model adjusting for clinical site of recruitment, no statistical interaction was observed between birthplace and use of the module (p=0.690).

Table A2-19. Test of statistical interaction of module with birthplace, in intent-to-treat sample, relative risk regression adjusting for clinical site of recruitment (n=2,231)

	p-value	RR	95% CI	
			Lower	Upper
Any Intervention Group	.051	1.18	0.99	1.40
Foreign-born	.029	1.21	1.02	1.16
Foreign-born* Intervention Interaction	.690	0.96	0.80	1.16
Clinical Site 1	.014	1.07	1.01	1.13

7.D.2 Impact of Tailored Materials (Specific Aim 1)

As discussed in Chapter 2, tailored health information generated by the algorithm – provided for the Intervention + Tailored participants, but not for those in the Intervention + Generic group – did not have an impact on the primary outcome for Specific Aim 1 (choice of an effective

contraceptive method). A logistic regression model, adjusting for clinical site, confirmed the lack of effect of tailored materials on choice of an effective method (Table A2-20).

Table A2-20. Logistic regression models of choosing an effective contraceptive method, comparing intervention arms to control, and one intervention arm to another, intent-to-treat sample

	Effect of Module: Comparing Module Users to Control	**Effect of Tailored Materials: Comparing Module Users who Received Tailored Materials**
	n=2,231	**n=1,901**
Intervention + Tailored	1.56 (1.23-1.98) p<0.001	0.90 (0.72-1.13) P=0.354
Intervention + Generic	1.74 (1.35-2.25) p<0.001	[Ref.]
Control	[Ref.]	Not included

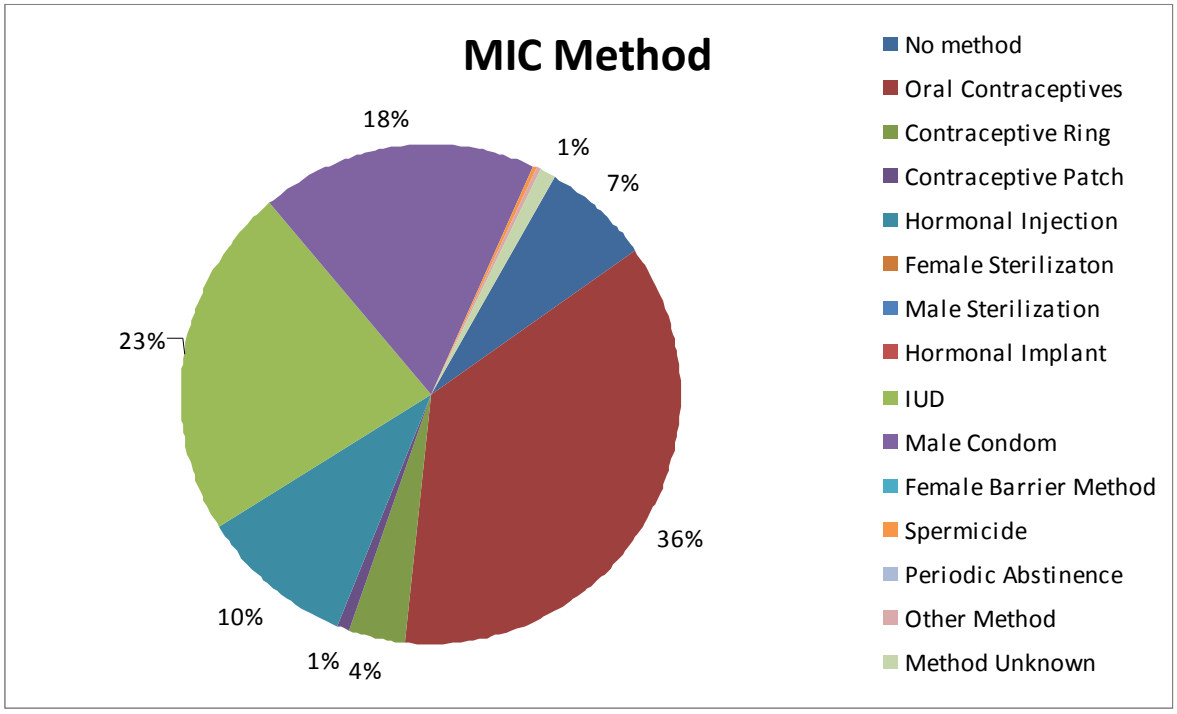
Note: *Analyses adjusted for clinical site*

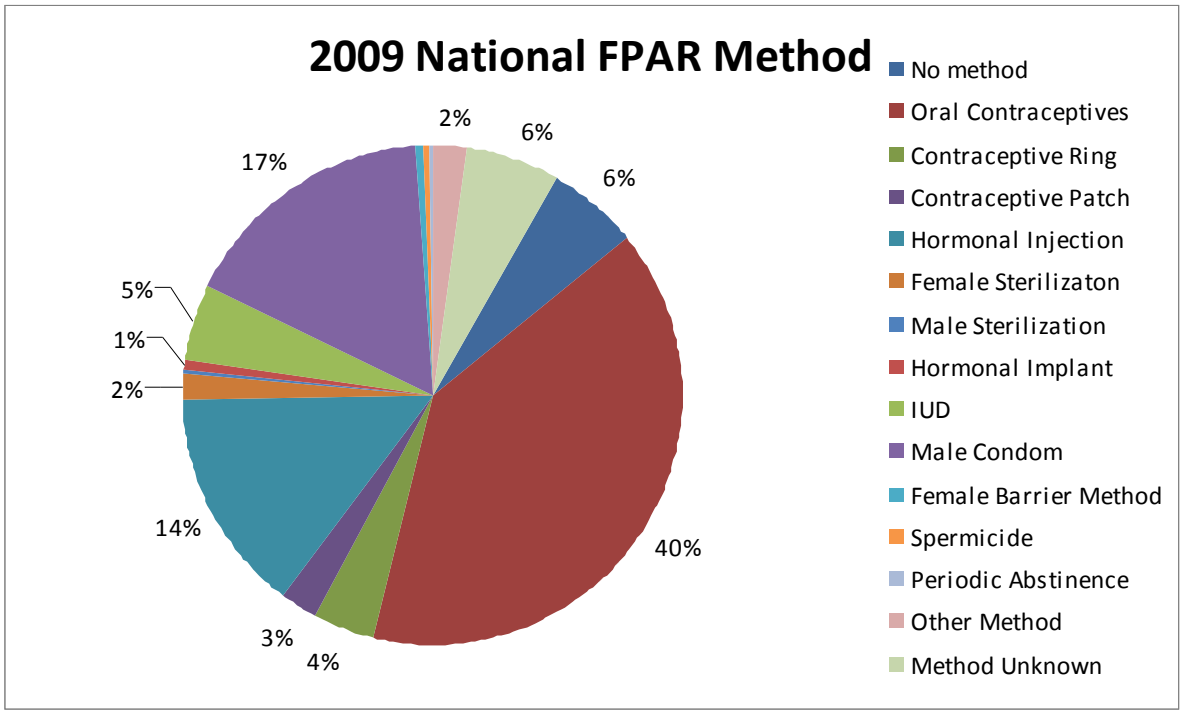
7.E EXTERNAL VALIDITY

The family planning centers at which the study was conducted receive funding to improve the availability of long-acting reversible contraceptive methods such as IUDs. As a result, the contraceptive method mix at the clinical network from which the study participants were recruited [f] differs from the method mix at all family planning centers that receive federal funding through the Title X family planning program. As shown in Figures A2-6a and A2-6b, in 2008, 23% of patients in the MIC network chose IUDs, compared to 5% of national Title X family planning patients as reported in the Family Planning Annual Report [215] .

[f] The clinical network includes 6 family planning centers; participants were recruited from 2 of the centers.

Figures A2-6a & A2-6b. Comparison of contraceptive method mix at recruitment centers, compared to National Title X Family Planning Annual Report data for all national centers, 2008





Note: *Charts prepared by Alicia Ventura, Clinical & Community Health Programs Unit, Public Health Solutions. FPAR is the Family Planning Annual Report; data reported in [215]*

8 APPENDIX 3: SUPPORTING ANALYSES FOR CHAPTER 3

8.A OPERATIONALIZATION OF OUTCOME

For analyses testing Specific Aim 2, the results of which are presented in Chapter 3, the primary outcome was choice of a method that was identified as a "best fit" by the algorithm underlying the contraceptive assessment module. The "best fit" status of the chosen method is calculated by the algorithm for participants in both the Intervention + Tailored and Intervention+ Generic arms. As shown in Table A3-1, all "best fit" methods are effective methods, but not all effective methods may be a "best fit" for the individual participant. The outcome data source for contraceptive method choice for these analyses is the patient self-reported contraceptive method choice as recorded in the end-of-visit survey (Appendix 1).

Table A3-1. Operationalization of primary outcome for Specific Aim 2, in relation to primary outcome for Specific Aim 1

Chose an effective method (Specific Aim 1)	Dichotomous primary outcome (Specific Aim 2)	Algorithm score category of chosen method
Yes	Yes	Best fit (Green)
No	This distribution of outcomes is not possible. All methods scored by the algorithm as a "best fit" are effective.	Best fit (Green)
Yes	No	Not recommended (Yellow)
No	No	Not recommended (Yellow)
Yes	No	Medically contraindicated (Red)
No	No	Medically contraindicated (Red)

As shown in Table 2-2, 73% of those in the Intervention + Tailored arm chose an effective method of contraception, compared to 76% in the Intervention + Generic arm. As shown in Table A3-2, the proportions of participants in the Intervention arms who chose an effective method that was not a "best fit" were, respectively, 15% and 16%. These proportions did not

differ significantly between the two intervention arms, consistent with findings presented in Chapter 2 and Chapter 3.

Table A3-2. Distribution of Specific Aim 1 and Specific Aim 2 outcomes among sample (n=1,454)

	Intervention + Tailored (n=814)	Intervention + Generic (n=640)
Effective and "best fit"	477 (58.6)	386 (60.3)
Effective but not "best fit"	122 (15.0)	102 (15.9)
Not effective	215 (26.4)	152 (23.8)

Chi-square test p=0.498

8.B EXCLUSION OF SUBJECTS FROM SPECIFIC AIM 2 ANALYSES

Of the 1,484 participants in the Intervention + Tailored or Intervention + Generic groups, 1,454 (98%) had at least one method scored by the algorithm as a best fit, but 30 had only “yellow” methods identified by the algorithm. No participant had all methods listed as medically contraindicated (“red”). The 30 participants for whom the algorithm did not identify a “best fit” method (n=20 in the Intervention + Tailored arm and n=10 in the Intervention + Generic arm) were excluded from analyses testing Specific Aim 2 (presented in Chapter 3).

The module responses for the excluded 30 participants excluded were reviewed to determine the reasons the module was not able to identify a “best fit” method. (The following reasons are not mutually exclusive.) The most common reason that a participant would have no methods identified as a “best fit” was if the participant skipped the set of questions asking about the three most important factors in a contraceptive method (q25_easyUse through q25_lessPerSymptoms), because this question assigns points in favor of several methods.

Among the 30 participants who were excluded because the module did not identify a “best fit” method, 57% (n=17) answered “I don’t know” (n=16) or “I don’t want to answer” (n=1) to this series of questions, compared to only 6% of the participants who were included in analyses for Specific Aim 2 (n=1,454). Response patterns in a series of questions about changes in menstrual patterns were another reason participants did not have a “best fit” method

identified: almost a quarter of the excluded participants (n=7) reported that they would not "be okay" with regular scheduled bleeding, but would also not "be okay" with no bleeding at all. Of the 30 participants for whom the module did not identify a "best fit" method, only 10 (33%) had any medical condition that would result in a contraindication for at least one contraceptive method, compared to 48% of those who were included in the analyses. Of the excluded participants, 5 had a history of high blood pressure, and 4 had a history of migraines with aura.

8.C ANALYSES TO TEST HYPOTHESES

8.C.1 Categorical algorithm ranking of chosen method

Analyses presented in Chapter 3 were repeated, using a categorical (rather than dichotomous) outcome for the algorithm's ranking of the chosen contraceptive method. Methods could be ranked by the module as a "best fit" (a method that is both effective and acceptable given the participant's responses to the questions); not recommended (a method that is not suitable for the participant given responses and/or less effective); medically contraindicated; a method recommended to all participants (abstinence or condoms); or no method. As shown in Table A3-3, 60% (n=871) of all participants chose a method that was a best fit for them given their responses to the module, while 8% (n=117) chose a method that was medically contraindicated. Confirming the findings of the analyses presented in Chapter 3, there was no significant difference in the distribution of the categorical outcome between the two intervention arms (Chi square test p=0.686).

Table A3-3. Categorical algorithm ranking of chosen contraceptive method, using self-report outcome data, among Intervention + Tailored and Intervention + Generic arm participants, by randomization arm (n=1,452)

Algorithm ranking of chosen method	Intervention + Tailored (n=813)	Intervention + Generic (n=639)
	n(%)	n(%)
Medically contraindicated (Red)	63 (7.7)	54 (8.5)
Not recommended	60 (7.4)	43 (6.7)
"Best fit" (Green)	478 (58.8)	393 (61.5)
No method chosen	129 (15.9)	95 (14.9)
Condoms (recommended to all)	83 (10.2)	54 (8.5)

Note: *Two participants reported choice of more than one method with different rankings by the module and were excluded from this analysis. Chi-square test of difference across randomization arms p =0.686*

Among the 117 participants who chose a contraindicated method, 52 (44%) had a history of migraine with aura and 18 (15%) were age 35 or over with a history of migraine and chose an estrogen-containing method; 11 (9%) had a history of gall bladder disease and chose combined oral contraceptives; and 8 (7%) had pelvic inflammatory disease within the last 3 months and chose an intrauterine device. Among women of reproductive age in the US, the prevalence of headaches is approximately 37%, and the prevalence of migraine is as high as 28%, presenting a challenge of prescribing contraception for these women [217, 218]. A recent analysis conducted among Mexican-American women in Texas comparing patients' self-screening for contraindications to the provider's screening for combined oral contraceptives found high sensitivity and specificity for self-screening (83.2%). In only 7% of cases participants indicated they had medical histories for which oral contraceptives would be contraindicated but the provider screening indicated that they would be eligible [72].

8.D ANALYSES TO ADDRESS POTENTIAL SOURCES OF BIAS

8.D.1 Comparing Intervention + Tailored to Intervention + Generic participants

The descriptive analyses presented in the tables in Chapter 3 were repeated, comparing the two intervention arms to each other to ensure that they were comparable to each other in terms of the independent variables included in the analyses. As shown in Table A3-4, the two intervention arms did not differ significantly on the sociodemographic characteristics tested.

Table A3-4. Sociodemographic characteristics of Intervention + Tailored and Intervention + Generic participants included in analyses, by randomization arm (n=1,454)

	Intervention + Generic (n=640)		Intervention + Tailored (n=814)		Significance test of difference across arms
Characteristic	**n**	**%**	**n**	**%**	**Chi-square (p)**
Age category					0.286
16-19	101	15.8	115	14.1	
20-24	142	22.2	162	19.9	
25-29	144	22.5	201	24.7	
30-34	122	19.1	184	22.6	
35 and older	131	20.5	152	18.7	
Race/Ethnicity					0.869
Latina, any race	457	71.9	568	70.7	
Non-Latina black	77	12.1	104	13.0	
Non-Latina, non-black	102	16.0	131	16.3	
Preferred module language					0.710
English	278	43.4	36.2	44.5	
Spanish	362	56.6	452	55.5	
Birthplace					0.192
US	141	22.1	203	25.1	
Other countries	497	77.9	607	74.9	
Insurance and income status					0.530
None/self-pay <100%FPL	319	51.3	382	48.4	
None/self-pay 100-149% FPL	43	6.9	62	7.9	
None/self-pay over 150% FPL	9	1.5	18	2.3	
Medicaid or other income-eligible public insurance	248	39.9	319	40.4	
Private insurance or HMO	3	0.5	8	1.0	
Clinical site of recruitment					0.247
Site 1	423	66.1	513	63.0	
Site 2	217	33.9	301	37.0	

Table A3-4, Continued

Characteristic	n	%	n	%	Chi-square (p)
Educational attainment					0.939
Less than high school	176	27.8	216	26.8	
High school graduate/GED	244	38.5	317	39.4	
Some college or more	214	33.8	272	33.8	
Frequency of computer use					0.199
Never	92	14.4	132	16.3	
Infrequent (< once/week)	65	10.2	100	12.3	
Once a week or more	482	75.4	580	71.4	

**FPL = federal poverty level*

As shown in Table A3-5, the two groups did differ on some of the contraceptive history, preference and priorities variables tested, with some of the comparisons reaching statistical significance (at alpha =0.05): those in the Intervention + Tailored arm, compared to those in the Intervention + Generic arm, were more likely to have experienced a problem with a method (Chi-square test p=0.041), more likely to prefer using a method once a month (p=0.042), less likely to prioritize safety with breastfeeding as a characteristic in a method (p=0.008), and more likely to have menstrual symptoms that require missing work or school (p=0.038). These apparent statistically significant results – occurring among the more than 40 tests of statistical significance required for Table A3-5 – may be attributed to type I error that one would expect as the result of multiple comparisons rather than systematic differences between the two groups. Therefore, the analyses presented in Chapter 3 combined both intervention arms.

Table A3-5. Contraceptive history, preferences, and priorities of Intervention + Tailored and Intervention + Generic arm participants included in analyses, by randomization arm (n=1,454)

Characteristic	Intervention + Tailored (n=640)		Intervention + Generic (814)		Significance test of difference across arms
Contraceptive history	**n**	**%**	**n**	**%**	**Chi-square (p)**
Ever used contraception	674	82.9	537	84.2	0.569
Contraceptive method used at start of visit [g]					
None	364	47.0	261	43.3	0.318
Oral contraceptives (combined or progestin-only)	164	21.1	125	20.7	
IUD (Paragard or Mirena)	130	16.8	99	16.4	
Condoms	48	6.2	48	8.0	
Injectable (Depo-Provera)	44	5.7	46	7.6	
NuvaRing	18	2.3	17	2.8	
Contraceptive patch	3	0.4	3	0.5	
Withdrawal	3	0.4	0	0.0	
Breastfeeding	0	0.0	3	0.5	
Female barrier methods (diaphragm, sponge, female condom)	1	0.1	1	0.2	
Contraceptive history	**n**	**%**	**n**	**%**	**Chi-square (p)**
Number of unintended pregnancies					0.323
None	491	60.4	362	56.6	
1 unintended pregnancy	210	25.8	178	27.8	
2 or more	112	13.8	100	15.6	
Not using contraception at first unintended pregnancy	76.6	249	219	79.3	0.432
Ever experienced a problem with a contraceptive method[h]	324	49.3	229	43.3	0.041

Notes: *Missing data not shown*

[g] *Participants who reported using more than one method were categorized according to method of highest typical use effectiveness. Participants who reported concurrent use of more than one hormonal method (n=27) were excluded.*

[h] *Asked only of participants who reported ever using contraception.*

Table A3-5, Continued

Characteristic	Intervention + Tailored (n=640)		Intervention + Generic (n=814)		Significance test of difference across arms
Contraceptive preferences	**n**	**%**	**n**	**%**	**Chi-square p**
Need to keep method private	455	57.4	379	60.9	0.192
Not OK to interrupt sexual activity to use method	552	69.5	441	70.4	0.727
When want to take action [i]					
Every time you have sex	176	23.2	165	27.4	0.089
Every day	198	26.2	133	22.1	0.086
Once a week	96	12.7	60	10.0	0.124
Once a month	110	14.5	65	10.8	0.042
Every three months	98	12.9	96	15.9	0.138
Longer than every three months	71	11.8	92	12.2	0.867
Permanent method	217	28.7	172	28.5	1.000
When want to become pregnant					0.987
Less than one year	16	2.0	15	2.4	
1-3 years	103	12.9	80	12.8	
3 or more years	199	25.0	156	25.0	
Not sure but definitely want to have a baby	227	28.5	173	27.8	
Never	251	31.5	199	31.9	
Contraceptive priorities					
Most important factors in a method [i]					
Easy to use	465	60.9	388	63.6	0.314
Very effective	466	61.1	358	58.7	0.376
Not very many side effects	308	40.4	239	39.2	0.658
Able to give regular monthly periods	202	26.5	170	27.9	0.583
No hormones	171	22.4	116	19.0	0.125
Do not need to interrupt sexual activity	143	18.7	127	20.8	0.340
Able to get pregnant quickly after stopping method	113	14.8	91	14.9	1.000
Inexpensive	111	14.5	74	12.1	0.204
Effective long term (3 months or longer)	86	11.3	72	11.8	0.799
Safe with breast-feeding	70	9.2	84	13.8	0.008
Gives fewer periods or no period	62	8.1	48	7.9	0.920
Decreases symptoms from period	61	8.0	51	8.4	0.843

[i] *Responses not mutually exclusive.*

Table A3-5, Continued

Characteristic	Intervention + Tailored (n=640)		Intervention + Generic (n=814)		Significance test of difference across arms
Sexual history	**n**	**%**	**n**	**%**	**Chi-square p**
Participant and partner status					0.942
Have sex only with each other	621	77.6	493	78.0	
Have sex with other people	24	3.0	16	2.5	
Not sure about partner's sexual activity outside the relationship	95	11.9	73	11.6	
Currently not having sex	60	7.5	50	7.9	
Number of male sexual partners in last year, mean (range)	1.4 (0-20)		1.4 (0-20)		ANOVA p=0.775
Medical history					
Any medical condition for which some contraceptive methods may be contraindicated	384	47.2	314	49.1	0.492
Menstrual symptoms require missing work or school sometimes or almost every month	181	23.1	111	18.3	0.034
Currently taking any medication for which some contraceptive methods may be contraindicated	2	0.2	1	0.2	1.000

8.D.2 Effect of tailored materials among non-users of contraception at start of visit

Analyses testing Specific Aim 2 were repeated, looking only at the Intervention + Tailored and Intervention + Generic arm participants who reported using no method of contraception at the start of their visit (n=625). Consistent with the main findings, participants in the Intervention + Tailored arm, who received tailored materials, were not significantly more likely than those in the Intervention + Generic arm to choose a "best fit" method (44% in Intervention + Tailored, 52% in Intervention + Generic), although the results were of borderline statistical significance (Chi-square test p=0.052).

8.E ADDITIONAL ANALYSES

8.E.1 Differences in contraceptive history, preferences, and priorities, by age group

Considerable attention has been paid in the body of literature to the contraceptive needs of young women age 16 through 24 [42, 124, 219-221] . While outside the scope of the analyses testing specific aims, the contraceptive history, preferences and priorities of intervention participants age 16 through 24 were compared to those age 25 and over. As shown in Table A3-6, young women age 16-24, compared to those age 25 and over, were less likely to be using a method of contraception at the start of their visit, were more willing to use contraceptive methods that require interrupting sex, were more likely to be in non-monogamous relationships and to be not sexually active at the time before their family planning visit, were less likely to have any medical condition for which some contraceptive methods may be contraindicated, but more likely to have menstrual symptoms that require missing work or school.

Table A3-6. Contraceptive history, preferences, and priorities of Intervention + Tailored and Intervention + Generic arm participants included in analyses, by age group (n=1,454)

	Age 16-24 (n=520)	Age 25+ (n=934)	Significance test of difference between groups
Contraceptive history	**n (%)**	**n (%)**	**Chi-square test p-value**
Using a method of contraception now	273 (52.5)	583 (62.8)	p<0.001
Ever used contraception	433 (83.3)	778 (83.6)	p=0.883
Number of unintended pregnancies			p=0.079
None	325 (62.5)	528 (56.6)	
1 unintended pregnancy	129 (24.8)	259 (27.8)	
2 or more	66 (12.7)	146 (15.6)	
Not using contraception at first unplanned pregnancy	160 (81.6)	308 (76.0)	p=0.142
Ever experienced a problem with a method	172 (33.3)	381 (41.2)	p=0.009
Contraceptive preferences			
Need to keep method private	315 (62.3)	519 (57.2)	p=0.063
Not OK to interrupt sexual activity to use method	327 (63.9)	666 (73.3)	p<0.001
When want to take action*			
Every time you have sex	28.5	23.2	p=0.031
Every day	23.8	24.7	p=0.742
Once a week	13.2	10.5	p=0.132
Once a month	18.4	9.8	p<0.001
Every three months	18.8	11.8	p=0.001
Longer than every three months	14.9	10.4	p=0.018
Permanent method	13.6	36.9	p<0.001
When want to become pregnant			p<0.001
Less than one year	10 (1.9)	21 (2.3)	
1-3 years	65 (12.7)	118 (13.0)	
3 or more years	197 (38.4)	158 (17.4)	
Not sure but definitely want to have a baby	165 (32.2)	235 (25.9)	
Never	76 (14.8)	374 (41.3)	
Sexual history			
Number of male partners in last year, mean (range)	1.7 (0-20)	1.2 (0-11)	ANOVA p<0.001
Participant and partner status			p=0.005
Have sex only with each other	384 (74.6)	730 (79.6)	
Have sex with other people	23 (4.5)	17 (1.9)	
Not sure about partner's sexual activity	59 (11.5)	109 (11.9)	
Currently not having sex	49 (9.5)	61 (6.7)	
Medical history			
Any medical condition for which some contraceptive methods may be contraindicated	215 (41.3)	486 (52.0)	p<0.001
Menstrual symptoms require participant to miss work or school sometimes or almost every month	128 (25.3)	164 (18.4)	p=0.003

**** Note:** responses not mutually exclusive*

9 APPENDIX 4: DATA COLLECTION FOR CHAPTER 4

9.A FOLLOW-UP SURVEY DATA COLLECTION PROCEDURES

Of the 1,983 participants in the as-treated analyses, a subset (n=329) were randomly selected for participation in a 4-month follow-up telephone interview on method continuation and adherence. Of those randomly selected, a total of 269 (81.5%) were successfully contacted and interviewed.

Telephone interviews were conducted by two trained, bilingual (Spanish/English) interviewers who were not aware of the randomization arm status of the participant. Interviewers made a minimum of 10 attempts to contact each participant by telephone before considering the participant lost to follow-up. Telephone contacts were made at varied times of the day, and varied days of the week.

Table A4-1 lists the wording of the questions, and the response options, for the follow-up telephone survey. The survey questions and response options were translated into Spanish using the same process outlined in Appendix 1.

In the second question of the follow-up survey (Q2), the interview data collection forms were completed by project staff with the contraceptive method that had been chosen on the day of the family planning visit, as reported by the participant to the End-of-Visit survey.

Table A4-1. Follow-Up Survey: Variable Names, Question Wording, and Response Options

Question number	Question text	Response options
Q1	Have you had any major changes to your health or reproductive goals since taking the survey four months ago?	Yes/No
Q2	Are you still using [chosen method(s) from End of Visit Survey]	Yes/No
Q3	[Depending on Method Chosen, if continued]	
The pill	Have you taken your pills in the past 2 weeks?	Yes/No
Progestin-only pills	Have you taken your pills in the past 2 weeks?	Yes/No
NuvaRing	Have you had a ring in place the past two weeks?	Yes/No
Depo Provera	Have you had your second shot?	Yes/No
Male condom	Have you used condoms every time you had sex?	Yes/No
Female barrier methods	Have you used [the barrier method] every time you had sex?	Yes/No
IUD	Is your IUD still in place?	Yes/No
Patch	Have you placed a patch in the past two weeks?	Yes/No
Q4	Why did you stop using that method? [If Q2=No]	[Open text]
Q5	What method of birth control are you using now?	
		None
		Patch
		Abstinence
		Withdrawal
		The pill
		Vaginal spermicides
		Progestin-only pills
		Rhythm method
		NuvaRing
		Tubal ligation
		Depo Provera
		Vasectomy
		Male condom
		Contraceptive implant
		Female barrier methods
		Breastfeeding
		IUD
Q6	Why did you choose to change to that method?	[Open text]

9.B ISSUES IN DATA COLLECTION

9.B.1 Random Selection Process

Project funding was not sufficient to enable follow-up interviewing of all participants in the trial; a subset of participants was therefore randomly selected to participate in the follow-up survey. Random selection was conducted using the random case selection process of SPSS 14.0 (Chicago, IL), stratifying by randomization arm. Every two weeks, using a sampling frame of the sequential ID numbers of participants who had completed participation in the main trial four months earlier, 10 to 25% of ID numbers were randomly selected. The bi-weekly selection process was repeated until a minimum of 100 participants in each randomization arm had been selected. As shown in Table A4-2 on the following page, the proportion of participants randomly selected increased as recruitment progressed to enable the project to reach the target number of participants (n=300).

Table A4-2. Number and proportion of participants randomly selected for participation in the follow-up survey, by selection date (n=329)

Selection date	N randomly selected	% selected
July 21, 2009	4	10%
August 5, 2009	3	10%
August 17, 2009	3	10%
September 1, 2009	4	11%
September 15, 2009	4	10%
September 29, 2009	7	10%
October 13, 2009	7	9%
November 3, 2009	7	14%
November 17, 2009	17	20%
December 1, 2009	15	19%
December 11, 2009	15	16%
December 21, 2009	15	18%
January 8, 2010	13	18%
January 22, 2010	19	20%
February 5, 2010	14	21%
February 19, 2010	14	19%
March 4, 2010	8	18%
March 19, 2010	11	18%
April 2, 2010	11	16%
April 13, 2010	6	18%
April 30, 2010	9	20%
May 17, 2010	12	20%
May 28, 2010	8	21%
June 11, 2010	11	20%
June 29, 2010	11	20%
July 9, 2010	24	23%
August 5, 2010	12	24%
August 27, 2010	13	25%
September 3, 2010	12	24%
September 17, 2010	6	25%
September 24, 2010	14	25%
Total	329	

9.B.2 Comprehension of follow-up survey questions

The first question on the follow-up survey, which had been used by colleagues at Emory University, was “Have you had any major changes to your health or reproductive goals since taking the survey four months ago?” This question, however, did not appear to result in reliable responses when compared to the responses to subsequent questions.

Of the 50 participants who reported (in response to Q2) that they had discontinued their method, 40 (80%) reported that they had not had any major changes to their reproductive goals. Of these 40 participants, however, 10 (25%) gave responses to an open-ended question (Q4) that indicated a change in reproductive goals and 9 (23%) cited physical side effects. Selected responses to the open-ended question about reasons for discontinuing their chosen method, among those who reported that they had not had changes to reproductive goals include:

> “Because I am no longer with my partner.”
>
> “Because I do not want to have another baby. I am confused because my partner wants another child but at this moment, I do not want to.”
>
> “Because I got pregnant.” (Cited by 4 participants in total)
>
> “Because I want to become pregnant.”
>
> “Because I want to have another baby.”
>
> “I broke up with my partner.”

This question was not used to code any of the outcomes presented in Chapter 4 (use of an effective contraceptive method 4 months after visit, continuation of chosen method, or adherence to continued method).

9.B.3 Limited Sample Size

Grant funding for the project did not allow follow-up surveying of all trial participants. The follow-up survey, originally designed with a projected sample size of 113 participants in each of two arms, distributed evenly across two arms, was powered (80% power and alpha of 0.05) to

detect a 20% difference from a baseline estimate of 75% continuation (for all methods). Baseline continuation rates were estimated from clinical data from Emory University. The sample size for the follow-up study as recruited (n=269), had only 93 participants in the Intervention + Tailored arm, 84 in the Intervention + Generic arm, and 92 in the Control arm. While the entire follow-up sample size of 269 is larger than the originally projected sample size of 226 (two arms of 113 subjects each), the two intervention arms could not be combined. Furthermore, exclusion of participants who chose no method of contraception on the day of the visit reduced the sample size for continuation and adherence analyses to 224. The impact of insufficient statistical power is discussed in Appendix 5.

10 APPENDIX 5: SUPPORTING ANALYSES FOR CHAPTER 4

10.A OPERATIONALIZATION OF OUTCOMES

10.A.1Use of effective method at follow-up

The first outcome studied in Chapter 4 (testing Hypothesis 3a) was use of any effective contraceptive method 4 months after the family planning visit. An effective method is one with fewer than 10 pregnancies per 100 women in one year of typical use [7], using the same dichotomous operationalization as described in Appendix 1 for analyses for Specific Aim 1. As shown in Table A5-1, participants who reported using an effective method at the follow-up survey, regardless of the method choice on the day of the family planning visit, were categorized as using an effective method at follow-up.

Table A5-1. Operationalization of outcome: use of any effective method at follow-up

Method choice on day of visit (Specific Aim 1)	Method use at 4-month follow-up survey	Hypothesis 3a outcome: Use of effective method at follow-up
Effective method	Effective method	Yes
Less effective or no method	Effective method	Yes
Effective method	Less effective or no method	No
Less effective or no method	Less effective or no method	No

The potential data issues of operationalizing contraceptive method use, discussed in Appendix 2 relating to contraceptive method choice, relate to the coding of the outcome for Hypothesis 3a. Table A5-2 summarizes contraceptive method use among the 269 participants at the time of the follow-up survey.

Table A5-2. Contraceptive method use at follow-up among follow-up sample (n=269)

Contraceptive method	n	%
IUD	58	21.6
DepoProvera	19	7.1
Pill	90	33.5
NuvaRing	13	4.8
Mini pills or progestin-only pills	2	0.7
Male Condom	36	13.3
Female Barrier Methods	1	0.4
None	49	18.2
Abstinence	1	0.4
Total	269	100%

10.A.2 Dual Method Use

As discussed in Appendix 2, a total of 11 participants reported in the End-of-Visit Survey that they chose more than one method on the day of the visit. Of these participants, 10 had chosen condoms with another method. None of the participants selected for the follow-up survey had chosen more than one method of contraception on the day of the visit, and as shown in Table A5-2, none reported using two or more methods at the time of the follow-up survey.

10.A.3 Abstinence

Because no typical use effectiveness data are available for abstinence, the one participant who reported using abstinence as a method of contraception at the time of the follow-up survey was excluded from the analysis testing Hypothesis 3a (use of any effective method of contraceptive method at follow-up), consistent with analytic procedures for Specific Aim 1 (Chapter 2).

The one participant who reported that she was using abstinence at the time of the follow-up survey had, as reported on the End of Visit survey, chosen oral contraceptives on the day of her family planning visit. This participant was coded as not continuing her method, and was coded as moving to a method of lower effectiveness. It should be noted that this single participant who reported using abstinence at follow-up is not the same individual who reported choosing abstinence as a method on the day of her visit.

10.A.4 Continued use of chosen contraceptive method (Hypothesis 3b)

The second outcome studied in Chapter 4 (testing Hypothesis 3b) was continued use of the same contraceptive method chosen at the family planning visit 4 months earlier, dichotomized as yes/no. Participants who reported that they were continuing use of the same contraceptive method chosen at the time of their visit – regardless of the method's effectiveness – were categorized as continuing their method. An affirmative response to the method-specific question on continuation (Q2, Table A4-1) was coded as continuing. A total of 45 participants who chose no method of contraception at the time of their visit (including patients who chose emergency contraception but no other method) were excluded from continuation analyses testing Hypothesis 3b, leaving a sample size of 224 for continuation analyses.

10.A.5 Adherence to chosen contraceptive method

While not included as an a priori hypothesis for Specific Aim 3, analyses of the follow-up dataset included examination of adherence to the chosen and continued contraceptive method, a dichotomous (yes/no) outcome. Analyses of adherence included the same 224 participants who were included in the continuation analyses. Patients were classified as adhering if they continued their method (responded affirmatively to Q2, Table A4-1) and responded affirmatively to the method-specific follow-up question about adherence (Q3, Table A4-1).

10.B ANALYSES TO TEST HYPOTHESES

10.B.1 Use of any effective contraceptive method at follow-up (Hypothesis 3a)

Overall, four months after participating in the intervention or control condition, 68% of the 269 participants in the follow-up analysis were using an effective method of contraception (cf Table A5-2). As shown in Table A5-3, the proportion using any effective method differed significantly

(with alpha set at 0.05) between the Intervention + Tailored and control arms, but not between the Intervention + Generic and control arms.

Table A5-3. Proportion and number in follow-up sample using any effective method of contraception at follow-up, by randomization arm (n=268)

Using Effective method at follow-up	Intervention + Tailored (n=84)	Intervention + Generic (n=93)	Control (n=92)	Total (n=269)
Yes	69 (74%)	58 (69%)	55 (60%)	182 (68%)
No	24 (25%)	26 (31%)	37 (40%)	87 (32%)
Chi-square test comparing each to the control arm	p=0.037	p=0.200	[Ref.]	

Note: *One participant using abstinence at follow-up excluded*

The effectiveness tiers of the contraceptive method choice at the time of visit and the time of follow-up were cross-tabulated. As shown in Table A5-4, the overall percentage of patients using an effective method (Tier 1 or Tier 2) declined slightly, from 71% at the time of visit, from 68% at follow-up. But the off-diagonal shading in Table A5-4 illustrates that there was some "flow" into and out of the dichotomous effectiveness outcome: 10 participants who had not chosen an effective method on the day of their visit transitioned to a more effective method at the time of follow-up, while 19 participants who had chosen an effective method on the day of their visit switched to a less effective or no method.

Table A5-4. Effectiveness tier of contraceptive method choice on day of visit, compared to effectiveness tier of method using at time of follow-up (n=268)

		Effectiveness Tier of method used at follow-up				
		Tier 1	Tier 2	Tier 3	None	Total
Effectiveness Tier of method chosen on the day of visit (patient self-report)	**Tier 1**	48	0	0	2	50
	Tier 2	4	120	5	12	141
	Tier 3	1	1	27	3	32
	None	6	2	5	32	45
Total		59	123	37	49	268

Note: *One participant using abstinence at follow-up excluded*

10.B.2 Continuation of chosen method

There were 34 participants who reported discontinuing their chosen method. As shown in Table A5-4, of these 34 participants, 22 (65%) moved to a less effective method or no method, and 6 (18%) to a more effective method, with the remainder moving to a different method in the same effectiveness tier [73]; these changes were not distributed differently across randomization arms (Chi-square p=0.865). Among those who discontinued their methods, the most common shift was to no method at the time of follow-up (n=12, or 35% of those who discontinued).

10.B.3 Characteristics of continuers who did not adhere

Overall, 85% (n=190) of the 224 participants in the continuation analyses reported that they continued use of their chosen method, and of these 190 patients who continued, 86% (n=164) reported adhering to their chosen method (wording of adherence questions, is in Table A4-1, Q3). As shown in Table A5-5, choosers and continuers of the pill and IUD were more likely to report adherence than continuers of other methods. Almost one-third (8 of 26) of participants who reported that they were "still using [condoms]" replied that they had not used a condom "every time [they] had sex" (cf Table A4-1).

Table A5-5. Self-reported contraceptive method choice on the day of visit of those who continued but did not adhere at 4 month follow-up, compared to those who continued and adhered (n=190)

	Continued and adhered		
	No	**Yes**	**Total**
The Pill	7	77	84
Mini pills or progestin-only pills	0	2	2
NuvaRing	4	8	12
DepoProvera	7	11	18
Male Condom	8	18	26
Female Barrier Methods	0	1	1
IUD	0	47	47
TOTAL	26	164	190

Chi square p<0.001

10.C ANALYSES TO ADDRESS POTENTIAL SOURCES OF BIAS

10.C.1 Selection bias in random selection for follow-up

Project funding was not sufficient to support contacting all trial participants for the follow-up survey; a subset of participants was randomly selected for the follow-up survey, stratified by randomization arm. Of the 1,983 participants in the as-treated analyses for Specific Aim 1 (Chapter 2), 329 were randomly selected. Analyses were undertaken to ensure that those who were randomly selected were representative of the entire sample of trial participants, testing each of the characteristics listed in Table 4-1 (Chapter 4). As shown in Table A5-6, those randomly selected for the follow-up survey did not differ significantly in any of the sociodemographic characteristics tested.

Table A5-6. Chi-square test results of sociodemographic characteristics of those randomly selected (n=329) and not selected (n=1,654) for inclusion in the follow-up survey

Characteristic	Chi-square test p-value
Age (5 categories)	p=0.271
Race/ethnicity (4 categories)	p=0.563
Language of module	p=0.585
Birthplace	p=0.206
Insurance (5 categories)	p=0.595
Recruitment site	p=0.461
Education (6 categories)	p=0.592
Computer use (5 categories)	p=0.581

Because participants who chose no method on the day of visit were excluded from analyses of continuation and adherence, and because choice of a “best fit” method could influence the likelihood of continuing a contraceptive method – a potential source of selection bias – the distribution of contraceptive method choice on the day of the visit was also examined for each randomization arm for the entire as-treated sample (n=1,983) and for those randomly selected for the follow-up analyses (n=329). As shown in Table A5-7, the distribution of method choice outcome on the day of visit did not differ significantly between the full as-treated sample and the

follow-up sample for any of the randomization arms (Chi-square test p=0.650 for Intervention + Tailored, p=0.442 for Intervention + Generic, and p=0.893 for Control).

Table A5-7. Distribution of contraceptive method choice on day of visit by effectiveness and "best fit" status, among those in as-treated sample (n=1,982) and those randomly selected for follow-up (n=328), by randomization arm

	Intervention + Tailored		Intervention + Generic		Control	
Contraceptive method choice on day of visit	**Day of Visit (n=834)**	**Follow-Up (n=114)**	**Day of Visit (n=650)**	**Follow-Up (n=102)**	**Day of Visit (n=498)**	**Follow-Up (n=112)**
"Best Fit"	57%	54%	60%	61%	--	--
Effective but not "Best Fit"	16%	19%	17%	16%	61%	63%
Tier 3	11%	9%	9%	13%	15%	15%
No method	16%	18%	15%	11%	24%	22%

Notes: *Participants who selected abstinence on the day of the visit (n=1) and at follow-up (n=1) excluded; "Best Fit" status of contraceptive method choice could not be calculated for control group participants because they did not complete all module questions. Chi-square test of differences between day of visit and follow-up by randomization arm, respectively: p=0.650, p=0.442, p=0.893.*

10.C.2 Selection Bias due to loss to follow-up

Of the 329 participants randomly selected for the 4-month follow-up telephone interview, 269 (81.5%) were successfully contacted and interviewed. The proportion interviewed did not differ significantly across randomization arm (Chi-square p=0.982). Compared to those who participated in the follow-up survey (n=269), those who did not participate (n=60) were younger (mean age 25 compared to 28, ANOVA p=0.006); the groups did not differ significantly on any of the other characteristics assessed in Table 4-1 or on the contraceptive method chosen at the time of their visit (Chi-square p=0.906).

Of those randomly selected for the follow-up interview, a total of 269 (81.7%) were successfully contacted and interviewed; the proportion interviewed did not differ significantly across randomization arm (Chi-square p=0.982). Compared to those who participated in the follow-up survey (n=269), those who did not participate (n=60) were younger (mean age 25 compared to 28, ANOVA p=0.006); age as a categorical variable (in 5-year increments) also differed across the two groups in a Chi-square test (p=0.042).

The analyses presented in Table A5-7 were repeated, comparing the method choice distribution for the entire as-treated sample (n=1,983) to that of the participants who completed the follow-up survey (n=269). Again, there were no statistically significant differences in the contraceptive method choice distribution between the two samples (those in the as-treated sample, compared to those who completed the follow-up survey) for any of the randomization arms (Chi-square test p=0.812 for Intervention + Tailored, p=0.457 for Intervention + Generic, and p=0.993 for Control).

10.C.3Potential confounding in continuation and adherence analyses sample (n=224)

Table 4-1, which includes the participants who completed the follow-up survey (n=269) indicates that the distribution of sociodemographic characteristics was not distributed statistically significantly differently across randomization arms, but the clinical site of recruitment differed significantly. The distribution of characteristics was also compared across randomization arms among the sample that was included in continuation and adherence analyses (n=224). As shown in Table A5-8, the same patterns were evident: sociodemographic characteristics did not differ, but clinical site of recruitment did. As with previous analyses, analyses of continuation and adherence were adjusted for clinical site of recruitment.

Table A5-8. Sociodemographic characteristics of continuation and adherence follow-up study sample, by randomization arm (n=224)

	Intervention + Tailored (n=78)		Intervention + Generic (n=76)		Control (n=70)		Total (n=224)		Test of difference across arms (p)
Characteristic	**Mean (sd)**		**Mean (sd)**		**Mean (sd)**		**Mean (sd)**		**ANOVA**
Age in years, mean (sd)	29.7 (7.3)		28.6 (7.5)		28.7 (7.6)		29.1 (7.4)		0.562
Weight in pounds, mean (sd)	148.3 (31.8)		146.1 (36.2)		139.2 (23.1)		144.8 (31.1)		0.218
	n	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**Chi-square**
Age category									0.934
16-19	8	(10.3)	9	(11.8)	9	(12.9)	26	(11.6)	
20-24	9	(11.5)	14	(18.4)	11	(15.7)	34	(15.2)	
25-29	21	(26.9)	23	(30.3)	19	(27.1)	63	(28.1)	
30-34	19	(24.4)	13	(17.1)	15	(21.4)	47	(21.0)	
35 and older	21	(26.9)	17	(22.4)	16	(22.9)	54	(24.1)	
Race/Ethnicity									0.524
Latina, any race	60	(77.9)	56	(77.9)	46	(66.7)	162	(73.0)	
Non-Latina black	5	(6.5)	9	(6.5)	9	(13.0)	23	(10.4)	
Non-Latina, non-black	12	(15.6)	11	(15.6)	14	(20.3)	37	(16.7)	
Preferred module language									0.632
English	26	(33.3)	31	(40.8)	26	(37.1)	83	(37.1)	
Spanish	52	(66.7)	45	(59.2)	44	(62.9)	141	(62.9)	
Birthplace									0.900
US	14	(17.9)	14	(18.4)	11	(15.7)	39	(17.4)	
Other countries	64	(82.1)	62	(81.6)	59	(84.3)	185	(82.6)	
Insurance and income status									0.217
None/self-pay <100%FPL	45	(60.8)	48	(64.0)	31	(45.6)	124	(57.1)	
None/self-pay 100-149% FPL	5	(6.8)	3	(4.0)	8	(11.8)	16	(7.4)	
None/self-pay over 150% FPL	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.5)	
Medicaid or other income-eligible public insurance	23	(31.1)	24	(32.0)	28	(41.2)	75	(34.6)	
Private insurance or HMO	0	(0.0)	0	(0.0)	1	(1.5)	1	(0.5)	
Clinical site of recruitment									0.026
Site 1	52	(66.7)	55	(72.4)	36	(51.4)	81	(36.2)	
Site 2	26	(33.3)	21	(27.6)	34	(48.6)	143	(63.8)	

Table A5-8, Continued

Characteristic	n	(%)	n	(%)	n	(%)	n	(%)	Chi-square
Educational attainment									0.640
Less than high school	27	(35.1)	20	(26.3)	20	(29.4)	67	(30.3)	
High school graduate/GED	28	(36.4)	31	(40.8)	31	(45.6)	90	(40.7)	
Some college or more	22	(28.6)	25	(32.9)	17	(25.0)	64	(29.0)	
Frequency of computer use									0.124
Never	19	(24.4)	14	(18.4)	13	(18.6)	46	(20.5)	
Less than once/month	9	(11.5)	3	(3.9)	2	(2.9)	14	(6.3)	
Monthly or weekly	24	(29.8)	26	(33.3)	27	(38.6)	77	(34.4)	
Every day	26	(33.3)	33	(43.4)	28	(40.0)	87	(38.8)	

10.C.4Potential confounding due to length of use of chosen method

It was hypothesized that long-term users of a contraceptive method would be more likely to continue use of their contraceptive method 4 months after the visit, compared to participants who chose a new method on the day of visit. If the proportion of patients who chose the same method they had been using at the start of the visit were not distributed evenly in the follow-up sample, this could confound the findings on continuation.

Because control group participants were not asked what method of contraception they were using at the start of their visit, analyses to test these assumptions could only be conducted comparing the Intervention + Tailored group to the Intervention + Generic group. As shown in Table A5-9, of the 224 subjects in the follow-up analyses, 71 were in the control group, and 13 did not respond fully to the questions in the module about contraceptive method use at the start of the visit (or responded inconsistently, e.g. reporting concurrent use of two hormonal methods such as Depo Provera and oral contraceptives), leaving 141 participants in the Intervention + Tailored and Intervention + Generic arms with data to allow a test for confounding.

Table A5-9. Number and proportion of Intervention + Tailored and Intervention + Generic arm participants who chose a new method of contraception on the day of the visit, by intervention arm among those in continuation sample (n=224)

Chose a new method on the day of visit	Intervention + Tailored (n=78)	Intervention + Generic (n=76)	Control (n=70)
	n (%)	n (%)	n (%)
No – Stayed with method	34 (44%)	36 (47%)	--
Yes – Chose a new method	36 (46%)	35 (46%)	--
Could not be determined	8 (10%)	5(7%)	70 (100%)

Notes: *Control group participants did not complete the module question that asked about the type of contraceptive method used at the start of visit. Participants in the intervention arms who skipped the question (n=9) or who responded that they were using more than one hormonal method at the start of visit (n=4) were excluded.*

As shown in Table A5-9, the proportion of Intervention + Tailored participants in the continuation analyses who had chosen a new contraceptive method on the day of their visit was the same as in the Intervention + Generic arm (46% for both arms). Among these 141 participants, those who chose a new method of contraception on the day of visit (n=71) were equally likely to continue use of their method 4 months later, compared to those who chose a method they had been using (89% in both groups). Confounding by the length of method use, therefore, is not a potential explanation for the difference between the Intervention + Tailored and Intervention + Generic arms.

10.C.5Potential information bias resulting from phrasing of adherence questions

Information bias may have resulted from an unclear phrasing of the adherence questions, particularly for participants who chose condoms on the day of their family planning visit. The follow-up survey question on adherence asked of participants who reported continued use of condoms (“Did you use a condom every time you had sex?”) did not have a response option to indicate that the person had not been sexually active in the last two weeks. Because participants who chose condoms were more likely to be in the control group (20%, compared to

6% in Intervention + Tailored and 13% in Intervention + Generic), misclassification of responses of those who were not sexually active as not adhering would bias away from the null.

10.D ADDITIONAL ANALYSES

10.D.1 Comparing outcome for Hypothesis 3a to outcome for Hypothesis 3b

Consistent with operationalization as laid out in Table A5-1, participants who chose an effective method of contraception on the day of their visit and who were using a different effective method of contraception at the time of follow-up after their family planning visit were classified as having the outcome for Hypothesis 3a=yes (using an effective method at follow-up) but outcome for Hypothesis 3b=no (did not continue chosen method). In analyses of the follow-up survey data, only 5 participants reported changing to a method in the same effectiveness tier between the day of their family planning visit and the follow-up survey (3 in the Control arm, and 2 in Intervention + Generic). As shown in Table A5-10, no consistent pattern in method switching was detected among these 5 participants.

Table A5-10. Cross-tabulation of contraceptive method choice on day of visit and use at follow-up, among participants in the continuation sample who changed to contraceptive method in same effectiveness tier (n=5)

	Contraceptive method used at time of follow-up survey			
Contraceptive method chosen on day of family planning visit (End of Visit survey)	**Pill**	**NuvaRing**	**IUD**	**Total**
NuvaRing	1	0	0	1
DepoProvera	0	1	0	1
IUD	0	0	1	1
Patch	2	0	0	2
Total	3	1	1	5

The differing findings between Hypothesis 3a (use of an effective method at follow-up) and Hypothesis 3b (continuation of chosen method) were examined. As shown in Table A5-11, of the 45 subjects included in tests of Hypothesis 3a (use of an effective method at follow-up;

n=269) but not Hypothesis 3b (continuation of chosen method; n=224), 7 were using an effective method at follow-up, 5 of whom were in the Control group (indicated in shading).

Table A5-11. Contraceptive method use at follow-up, among participants in the continuation sample who chose no method on the day of visit, by randomization arm (n=45)

Contraceptive method used at follow-up	Randomization arm	n
None	Intervention with generic	7
	Intervention with tailored	11
	Control	13
Pill	**Control**	**2**
Male Condom	Intervention with generic	1
	Intervention with tailored	1
	Control	3
Emergency Contraception	Intervention with tailored	1
IUD	**Intervention with tailored**	**2**
	Control	**3**

10.D.2 Alternative explanations for observed effect of tailored materials on continuation and adherence

Compared to the control group, participants in the Intervention + Tailored arm were significantly more likely to continue and adhere to their chosen method at follow-up, but those in the Intervention + Generic group were not. This finding stands in contrast to the lack of significant difference between the two intervention arms in the outcomes studied in Chapter 2 (choice of an effective method) or Chapter 3 (choice of a "best fit" method). Analyses separating participants who chose a new method on the day of their visit from those who did not (summarized in section 1.C.4.) ruled out choice of a new method as an explanation. Alternative explanations for the observed effect of tailored materials at follow-up were examined.

10.D.2.a Choice of a "best fit" method

As summarized in Table 3-3 and Table A5-7, no statistically significant differences were observed between the Intervention + Tailored arm and the Intervention + Generic arm in the proportion of participants who chose a method of contraception that was a "best fit" for them

based on their responses to the module questions. Furthermore, in tabular analyses among intervention arm participants in the continuation analyses (n=154), participants who chose a "best fit" method (n=105) were no more likely to continue their chosen method compared to those who did not chose a "best fit" method (88% compared to 89%, Chi-square test p=0.793).

10.D.2.b Specific method choice at time of visit

Method choice on the day of visit, using the self-report method data, was compared method-by-method between the two Intervention arms (n=1,484) to determine if those in the Intervention + Tailored arm, compared to those in Intervention + Generic arm, were more likely to choose methods that are associated with higher rates of continuation and adherence in the general population such as IUDs [73]. The distribution of the specific contraceptive method choice on the day of the family planning visit did not differ significantly between the two intervention groups (Chi square p=0.183); the proportion who chose IUDs did not differ (22% and 24%, respectively), nor did the proportion who chose oral contraceptives (36% in both arms).

10.D.2.c Low statistical power

As acknowledged in Appendix 4, continuation and adherence analyses were statistically under-powered, a limitation that has occurred for other studies with similar aims [129]. Sensitivity analyses were conducted to determine whether inadequate power was an explanation for the lack of significant differences in continuation between the Intervention + Generic and Control arms. As shown in Table 4-2, 82% of those in the Intervention + Generic arm continued their method, compared to 77% in the Control arm (Chi-square test of the difference p=0.510); maintaining the distribution of the outcome and the randomization arm, but doubling the sample size equally, the p-value of the Chi-square test was only reduced to p=0.280.

10.D.2.d Small sample size

Given the small sample size, the movement of a small number of participants had an impact on the statistical significance of follow-up analyses. This impact was compounded by differences in the denominator by randomization arm. As shown in Table A5-12, in follow-up analyses the proportion of participants in the Intervention + Tailored arm who chose no method on the day of their visit did not differ significantly from the proportion in the Intervention + Generic arm (16% compared to 10%, Chi-square test p=0.192). While the number and proportion of participants excluded from continuation and adherence analyses did not differ across randomization arms, it did drastically reduce sample sizes.

Table A5-12. Number of participants in the follow-up sample who chose no method of contraception on the day of visit, by randomization arm (n=269)

	Intervention + Tailored (n=93)	Intervention + Generic (n=84)	Control (n=92)
Chose no method on day of visit, excluded from continuation analyses	15 (16%)	8 (10%)	22 (24%)
Chose any method on day of visit, included in continuation analyses	78 (84%)	76 (90%)	70 (76%)

The possibility of over-fitting the logistic regression model was considered as an explanation for the observed differences. The distribution of the continuation outcome was cross-tabulated with the clinical site of recruitment and the randomization arm to confirm that none of the cell counts were 0, but three cells had counts with fewer than 5 observations. As shown in Table A5-13, only 4 participants in the Intervention + Tailored arm did not continue their chosen method.

Table A5-13. Cross-tabulation of continuation outcome at follow-up with randomization arm and clinical site of recruitment (n=224)

		Continued chosen method			
Clinical site recruitment	**Randomization arm**	**No**	**Yes**	**% by arm and site**	**% by site**
Site 1	Intervention + Tailored	3	49	94%	85%
	Intervention + Generic	12	43	78%	
	Control	6	30	83%	
Site 2	Intervention + Tailored	1	25	96%	84%
	Intervention + Generic	2	19	90%	
	Control	10	24	71%	

Because cell counts were quite low, with 3 cells having a count of less than 5, Fisher's exact test was conducted for these results, unstratified by clinical site of recruitment. The results remained statistically significant (Fisher's p-value=0.0037; point probability of observing the exact table given marginals=0.0001).

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